MPSC Audit Summary

OPO code: 34451L
Date of Survey: August 30-31, 2016
Review Period: July 1, 2014 – July 1, 2016
Total # of donor records:

- OPTN Policy review: 21
- Critical Data: 30 (20 reviewed on Attachment 1a, 12 reviewed on Attachment 1c [2 records on Attachment 1a were also reviewed on Attachment 1c])
- DDR and DonorNet® Data Validation: 5

Clinical score: 97 % **Exceptional Concerns:** Please note the attached SBAR and CMS Report and see separate PDF for additional information submitted by the OPO (as requested by the MPSC Chair).

Potential Violation of Policy	Issue	OPO's Response
OPTN Policy 2.2 #5 requires the OPO to verify that death is pronounced according to applicable laws.	Three of 46 donor records did not have documentation verifying death was pronounced according to applicable laws. [redacted] – Death pronouncement by physician not included in the donor record. (Pronouncement made by Nurse Practitioner without physician signature.) Documentation of clinical exam consistent with brain death not included in the donor record. Upon request, clinical exam provided by OPO reports patient with "minimal gag reflex" intact. [redacted] Documentation of a clinical exam consistent with brain death not included in the donor record and could not be produced by the OPO upon request. [redacted] – Documentation of a confirmatory test for brain death was not in the donor record. Apnea test was aborted due to donor instability.	The OPO's state "law does not exist as to how brain death declaration must occur nor is [the OPO] aware of any federal laws or statutes that exist in regards to how brain death declaration is to be performed in [the OPO's state]. While there are guidelines for determining brain death in [the OPO's state], these are only guidelines and not law. Since its inception, the [OPO] has relied on the hospital expertise only to pronounce brain death. [The OPO's] Policy Verification and Documentation of Brain Death and practice has been to ensure a copy of the hospital brain death documentation is obtained and placed in the donor chart. This documentation per policy has been to ensure it includes that the patient is brain dead, the date/time and a signature by a physician. Staff were inconsistently verifying this documentation. [The OPO] did not have a process for ensuring the integrity of the brain death process. Root cause: Inconsistent verification of documentation and no federal law or state statute defining proper documentation of brain death. Lack of internal process for verifying hospital policy is followed or for ensuring integrity of brain death process. Corrective Action Plan and Estimated Completion Dates: A containment plan was put into place on August 31, 2016. All Quality, Organ Services, Family Services, and Professional Services staff could not sign into our electronic medical records system until they acknowledged receipt of information regarding the containment plan. The acknowledgement notice stated the following: '1) Moving forward, the Family Services Coordinators (FSCs) will be required to ensure that a negative clinical exam and apnea test are documented in the hospital chart and that a copy is made and placed in [the OPO's] chart along with the documentation of brain death pronouncement by a physician. 2) If

		an NP is documenting the brain death examination, the note must be co-signed by the attending physician that they are working under the direction of. If not co-signed, it cannot be accepted and [the OPO] will not proceed with organ recovery until accurate documentation is received from the hospital. This aligns with hospital contract language stating that 'the determination of death for a Potential Donor shall be made by the Donor's attending physician or by the physician responsible for certifying death at the Hospital.' 3) The FSCs and Organ Recovery Coordinators (ORCs) will add to their hand off/report (documented on the Clinical Pathway) that they have reviewed the documentation of the clinical exam, apnea test, and ancillary procedures (if applicable) and that a copy of these items and the death note have been placed in [the OPO's] chart. 4) The Clinical Quality Assurance Coordinators will be trained that when reviewing donor charts, documentation of a negative clinical exam and apnea test must be present in [the OPO's] chart along with a proper brain death note. Ancillary testing might also be present if performed. Acknowledgement of this notice confirms your understanding of these requirements and indicates your ability to comply with these requirements as stated above. All questions and concerns should immediately be directed to your manager." The above was a containment plan implemented immediately while Member Quality was onsite on August 31, 2016. Since then, the following corrective actions will supersede this immediate containment plan. 1. An emergency meeting of [the OPO's] Advisory Board will be held by October 5, 2016 where the Advisory Board will determine minimum standards as to what must be documented in the hospital's brain death note in order for [the OPO] to accept it as a suitable brain death declaration note. This will include that all brain death declarations must be completed by a MD or DO. The [OPO's] Chief Medical Officer will also be part of this meeting in determining standards. 2. Policy Verification and Documentation of Brain Death will be updated by October 9, 2016 to reflect that [the OPO] will follow each individual hospital policy for brain death and that at a minimum the recommendations from the Advisory Board as to brain death documentation must occur. Additional updates to this policy will include: • all brain death documentation is uploaded into the appropriate donor case in the 'BD Documentation' section of the electronic medical record system. • the organ recovery coordinator/family services coordinator must call the administrator on call (AOC) and have the AOC verify that the brain death note documentation matches the hospital policy and at a minimum has the requirements that the Advisory Board recommended.

		• the brain death documentation to be verified by the AOC should be reviewed from the attachments section in the electronic medical records system. This review by the AOC will be documented as a case note in the electronic medical record system. 3. An emergency meeting of [the OPO's] Governing Board Executive Committee will be held by October 10, 2016 to approve the recommendations to Policy Verification and Documentation of Brain Death that was recommended by the Advisory Board. Additionally, the policy will be shared at the next board meeting with all governing board members. 4. Once the policy has been reviewed and approved by the Executive Committee, the Organ Services, Professional Services and Family Services staff will be trained on the policy by October 13, 2016. 5. [The OPO's] work instruction Organ Chart QA Process will be created to reflect the key elements that need to be verified as it relates to documentation regarding pronouncement of brain death per Policy Verification and Documentation of Brain Death. This will be implemented and Organ Services, Quality Assurance Coordinators and Family Services Coordinators will be trained no later than October 13, 2016 on WI Organ Chart QA Process. 6. The [OPO's] Professional Services staff will do a 100% review of all organ potential hospital brain death policies by September 28, 2016. Each of the hospital policies on brain death will be uploaded into the iTransplant medical charting system for access by the organ recovery coordinators, family services coordinators, professional services coordinators, quality assurance coordinators and any other applicable staff. 7. In the event that an organ hospital does not have a policy on brain death, the professional services staff or a member of leadership will make contact with the hospital to ensure a brain death policy is created and implemented. This contact will be completed by October 5, 2016 and it will be stressed that a policy needs [to be] implemented in the next 60 days. 8. The Organ Services new coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016. 9. Professional Services staff, President/CEO and Chief Medical Officer will provide communication to all organ hospitals regarding the necessity to pronounce brain death according to hospital policy but also in regards to the minimum requirements for pronouncing brain death that the [OPO] Advisory Board recommends and the Executive Committee approves. This will be completed by October 13, 2016. 10. [The OPO's] form ORG-002 Clinical Pathway will be updated to ensure brain death is documented properly and reviewed by the AOC. The Clinical Pathway will be updated by October 13, 2016, and family services, organ

<table>
<tr><td></td><td></td><td>services and quality assurance coordinators will be trained by October 13, 2016.
11. The Organ Services' new coordinator orientation, Family Services' new coordinator orientation, and new Clinical Quality Assurance Coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016.
<u>Effectiveness assessment:</u>
Within the electronic medical record system, there is documentation completed on every case that lists the methods used to pronounce brain death. A report will be built to monitor those fields and ensure that the proper methods are being utilized to pronounce brain death. The report will be run daily and emailed to the Managers of Family Services and Organ Services so that they can ensure the information is correct and present in the chart. If documentation is not present they will follow up with the appropriate staff immediately. This will be implemented by October 13, 2016.
The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including... pronouncement of death documentation... to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee, will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016."</td></tr>
<tr><td>Critical Data, Accuracy of serologies</td><td>2 of 20 donors' serology results were entered incorrectly in UNet^{SM}.
<table><tr><th>UNet^{SM} documentation</th><th>Donor Record documentation</th></tr><tr><td>HTLV = Not Done</td><td>HTLV = Negative</td></tr><tr><td>EBV IgG = Negative
EBV IgM = Positive</td><td>EBV IgG = Positive
EBV IgM = Negative</td></tr></table></td><td>"HTLV is a serology that is not routinely run by our organization on organ donor cases, but is completed on select tissue donor cases at the request of certain tissue processors. The test is ordered/added to the testing panel by the tissue Team Leaders after tissue has been recovered. The results can take up to 5-7 days to receive. Previously, the addition of the HTLV test was not communicated between tissue and the organ Clinical QA Coordinators (the organ chart is looked at separately from the tissue chart and by different coordinators); therefore, the coordinator completing the DDR may not have been aware of an HTLV result needing to be corrected within the DDR.
The coordinator transposed the results when they were entered into Tiedi. When this occurred [the OPO was utilizing a different] electronic medical record system. The results had to be manually entered into Tiedi. We now</td></tr>
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		utilize the Transplant Connect/iTransplant electronic medical record system and the DDR is completed through an import of information pulled from iTransplant into Tiedi. Lack of process for verifying documentation. Root cause: Lack of a verification process resulting in a lack of communication. Corrective Action Plan and Estimated Completion Dates: 1. Serology results were corrected in Tiedi on September 15, 2016. 2. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDi by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016. 3. On shared organ and tissue cases, a QA team member will share HTLV results with the organ transplant programs. This is current practice and will remain part of the continuing process. 4. These changes will be reflected in [the OPO's] work instruction WI-Completing the Deceased Donor Registration. This will be implemented no later than October 5, 2016. 5. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016. 6. A report will be created enabling Quality Assurance staff to monitor the tests that are pending for both organ and tissue cases so that they can follow up on obtaining results. This will be implemented no later than October 13, 2016. 7. [The OPO's] Form Clinical Pathway and DCD Clinical Pathway will be updated to require a review of serologies entered into the EMR by the AOC. These forms will be updated by October 5, 2016, and family services, organ services and quality assurance coordinators will be trained by October 5, 2016. Effectiveness Assessment: Compliance will be measured through our internal audit process. Internal audit 004 'Organ Donor Suitability & Positive Serologies' will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart on cases where organ and tissue was recovered. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified... An initial QA check of critical information including... serology results... will be performed to ensure critical

		items identified in this CAP are completed accurately."
OPTN Policy 2.2 requires that OPOs must maintain documentation of an archived serum sample in the donor record.	2 of 21 donor records did not have documentation of an archived serum sample in the donor record.	"This occurred because we did not have any checks within the QA process to ensure that the statement was on the final HLA report received from the lab who archives the serum for us. They did produce updated documentation during the audit verifying that there was archived serum available for these two donors. Root cause: Lack of QA process Corrective Action Plan and Estimated Completion Dates: 1. All donor records from August 1, 2015 through current have been checked to ensure that the statement regarding an archive sample is present on the final report received from the lab archiving serum for organ donors. 2. [The OPO's] work instruction WI-ORG-068 will be created to reflect that all final HLA reports must have the statement '1.5 mL of serum is archived on this donor and will be saved for a minimum of 10 years.' If the statement is not present, the lab will be contacted by the Clinical QA Coordinator to find out if there is archive serum at the lab. If there is, an amended report will be requested. If there is no serum archive, a reportable event will be written and the investigation will be completed and documented through the CAPA process. This will be implemented no later than October 5, 2016. 3. The Clinical QA Coordinators will be trained on WI-ORG-068 by October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 015 'Organ Donor Records' will have an audit item added where the auditor will perform a random chart sampling to verify that the statement '1.5 mL of serum is archived on this donor and will be saved for a minimum of 10 years' appears on all final HLA reports sampled. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified."
OPTN Policy 2.5 requires donor records to have a correctly calculated hemodilution calculation for serological testing.	3 of 21 donor records had a serology draw time different from the draw time on the hemodilution worksheet.	"Internal policies and work instructions were not specific enough with regards to how the hemodilution needs to be completed. Specific information was outlined regarding blood products and colloids, but little guidance was given in regards to documenting crystalloids; therefore, documentation was inconsistent from one coordinator to another. Proper education for the Organ Recovery Coordinators related to the hemodilution calculation, specifically when crystalloids were a factor, was lacking." Root cause: Lack of training and competency. Corrective Action Plan and Estimated Completion Dates: 1. [The OPO's] forms ORG-002 Clinical Pathway and ORG-052 DCD Clinical

		Pathway will be updated to reflect that the blood bank needs to be contacted prior to completing the hemodilution on all cases to confirm the amount of blood products released/administered to the patient. If available, the blood administration records must be copied and placed in the donor record. If not available, it must be documented why they could not be obtained. This will also be updated in policy ORG A8.000 Serology Hemodilution Qualification. These updates will be made no later than October 5, 2016. 2. All Organ Services staff and Clinical Quality Assurance Coordinators will be trained on the policy and form updates prior to implementation and no later than October 5, 2016. 3. The Organ Services and Quality Assurance staff will be retrained on the hemodilution calculation. This education will include the rationale for performing the hemodilution, the components of the hemodilution (blood products, colloids, and crystalloids) and how they affect the sample, how to properly document the hemodilution, and what to do if the sample is found to be hemodiluted. There will also be a test to assess knowledge and understanding of the material presented. All staff will need to pass the test/assessment with 100%. This will be complete by all staff affected no later than October 5, 2016. 4. The Organ Services and Quality Assurance staff will be tested on hemodilution concepts, at a minimum, annually, once being released from orientation. The orientation training over hemodilution will also be assessed and updated to include what is outlined above and will be implemented no later than October 5, 2016. An initial QA check of critical information including... hemodilution... will be performed to ensure critical items identified in this CAP are completed accurately."
OPTN Policy 2.8 requires OPOs to have a urinalysis within 24 hours of cross clamp.	1 of 21 donor records did not have a urinalysis within 24 hours of cross clamp.	"A urinalysis was conducted within 24 hours of cross clamp, but the results were not documented in the electronic medical record and were thus not available at the time of inspection to the inspectors. Root cause: Lack of verification process for ensuring that tests that were performed without results being received prior to the OR were obtained after procurement. Corrective Action Plan and Estimated Completion Dates: 1. The urinalysis results were obtained from the donor hospital and documented in the donor record [after the site survey]. 2. A checklist (has been assigned ORG-098 Case Hand Off Report as an identifier) will be made for Organ Recovery Coordinators to complete at the end of a case in order to communicate to the QA staff any testing that needs [to be] followed up on post case (i.e. pending tests, pending biopsy reports, etc.). The checklist will be implemented no later than October 5, 2016.

		3. The checklist will be added to [the OPO's] policy ORG C1.000 Local Donor Chart Documentation and Completion. The policy will be updated and effective no later than October 5, 2016. 4. [The OPO's] forms ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that prior to entering the OR, the ORC must verify that a urinalysis with micro was performed within 24 hours of when cross clamp is expected to occur. If one has not been performed that will meet this timeframe, a urinalysis with micro will be ordered. These forms will be updated and effective no later than October 5, 2016. 5. [The OPO's] forms ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm urinalysis results of no more than 24 hours prior to entering OR are in the EMR. These forms will be updated and effective no later than October 5, 2016. 6. An automated report will be created and sent to QA weekly that lists the donors from the week, cross clamp date and time, and date and time of the latest U/A documented in the OPO EMR. This will be reviewed by the Manager, Business Analytics and Regulatory Compliance with the QA team to ensure compliance. This will be implemented no later than October 13, 2016. 7. All Organ Services and Quality Assurance Coordinators will be trained on the new form, the updated clinical pathways, and policy updates no later than October 5, 2016. An initial QA check of critical information including... verification an U/A was performed within 24 hours of cross clamp... will be performed to ensure critical items identified in this CAP are completed accurately."
OPTN Policy 2.15.C (previously 2.15.B) requires OPOs to document lot numbers of all flush solutions and/or additives.	3 of 21 donor records did not have documentation of a flush solution or additive lot numbers.	"The solutions and/or additives were for products brought into the OR by either out-of-state centers or the local thoracic teams. [The OPO's] Organ Recovery Coordinators failed to remember to obtain the necessary information and when the transplant centers were contacted they did not have record of the information needed. For abdominal recoveries performed by our local transplant centers, this information is captured in our inventory system. For all other recoveries we rely on the Organ Recovery Coordinators to remember to obtain the information from the other transplant centers involved, but there is no visual reminder currently. Root cause: Lack of appropriate forms, processes, and accountability measures. Corrective Action Plan and Estimated Completion Dates: 1. The Verification of Donor Information form (ORG-063) will be updated to include fields to document the solutions, additives, lot number and expiration dates of the items used in the recovery of the organs. This will be implemented no later than October 5, 2016. 2.[The OPO's] Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm fields to

		document the solutions, additives, lot number and expiration dates of the items used in the recovery of organs have been completed on ORG-063. These forms will be updated and effective no later than October 5, 2016. 3. Policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs will be updated to reflect where the lot and expiration information will be captured for all solutions and additives used in the OR by out-of-state centers and local thoracic transplant centers. This will be implemented no later than October 5, 2016. 4. All ORC staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates as well as the importance of documenting this information no later than October 5, 2016. Effectiveness assessment: Internal audit 007 Organ Donor Management, Allocation, and Recovery contains an item where the lot/expiration information needs to be verified in a random sampling of charts. This item will be updated to include that the random sampling of charts must include cases where either out-of-state recovery teams or local thoracic teams were involved in the recovery of organs will be checked to verify that all lot and expiration information is present for the solutions/additives used in the OR. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified."
OPTN Policy 16.5 (previously 16.6) requires donor records to have complete documentation verifying the accuracy of the organ and vessel packaging labels.	9 of 21 donor records contained a generic verification statement citing outdated OPTN Policy. (Policy 5.0) 1 of 21 donor records did not have documentation of two individuals verifying packaging and labeling at the same time. One staff member signed the form one hour after cross clamp; the other staff member signed the form two days after cross clamp.	Regarding the 9 cited records: "Form ORG-063 Verification of Donor Information and Packaging/Labeling was updated to reflect the change from OPTN Policy 5.0 to OPTN Policy 16 on July 1, 2015. For the cases listed, OPO staff utilized a version of the form that was printed from the OPO EMR which did not include the updated language. There was not clear communication that the OPO form ORG-063 should be used in order to ensure compliance. Root cause: Lack of communication between quality and organ staff as to proper form to use. Corrective Action Plan and Estimated Completion Dates: 1. The best practices 'Verification for Accuracy of Documentation and Packaging of Transplantable Organs' form provided by the UNOS audit staff will be implemented (has been assigned ORG-097 as an identifier). It will be referenced in policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs and ORG A13.000 Packaging and Labeling of Organs. This form and policy updates will be implemented no later than October 5, 2016. 2. All Organ Services staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates prior to implementation and

		no later than October 5, 2016." Regarding the 1 cited record: "The second verifier failed to sign the form when the verification took place and instead signed the form two days later when it was caught by another coordinator during review. Root cause: ORC did not follow policy. Corrective Action Plan and Estimated Completion Dates: 1. The best practices 'Verification for Accuracy of Documentation and Packaging of Transplantable Organs' form provided by the UNOS audit staff will be implemented (has been assigned ORG-097 as an identifier). It will be referenced in policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs and ORG A13.000 Packaging and Labeling of Organs. This form and policy updates will be implemented no later than October 5, 2016. 2. [The OPO's] Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm two individuals have verified organ and vessel packaging and labeling at the same time. These forms will be updated and effective no later than October 5, 2016. 3. All Organ Services staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates prior to implementation and no later than October 5, 2016. 4. Previously, reportable events were not consistently initiated when signatures were missing from ORG-063, but instead correction requests were initiated. WI-ORG-068 will be created and reflect that if the verification does not take place at the same date/time for both coordinators involved, or if there is a missing signature, date, or time on the 'Verification for Accuracy of Documentation and Packaging of Transplantable Organs' (has been assigned ORG-097 as an identifier) form a reportable event must be initiated and a case note must be written by the ORC as to why the procedure was not followed. This will be implemented no later than October 5, 2016 and all Organ Services and Quality Assurance staff will be trained on these changes prior to the implementation date. Effectiveness assessment: ...An initial QA check of critical information including... accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097) will be performed to ensure critical items identified in this CAP are completed accurately."

Administrative score: N/A	**Exceptional Concerns:** None	
Potential Violation of Policy	**Issue**	**OPO's Response**
Accuracy of DDR Information	4 of 5 forms contained a total of 13	"Root cause:

	errors.	Lack of alignment of processes for Organ department staff entering and validating DDRs and Quality Services staff performing quality check of donor record. Lack of training and competency. Corrective Action Plan and Estimated Completion Dates: 1. All information identified by site surveyors was corrected in Tiedi September 18, 2016. 2. When the Clinical Quality Coordinator is ready to close a chart, one of the final steps will be to run an audit report to see if any fields that populate into the DDR have changed since the date the DDR was submitted. This will be included on WI-ORG-068 Organ Chart QA Process. These will be implemented no later than October 5, 2016. 3. All Quality Assurance staff will be trained on the process change and the work instruction no later than October 5, 2016. 4. A report that can pull the serial data from the OPO EMR into the DDR will be implemented no later than October 13, 2016. 5. [The OPO's] form ORG-052 DCD Clinical Pathway will be updated to reflect that vital signs must be documented every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death. These updates will be made by October 5, 2016. 6. All Quality Assurance and Organ Recovery staff will be trained on the process change, updated pathway, and updates to the work instruction no later than October 5, 2016. 7. Family Services staff will receive education regarding the completion of the authorization/disclosure paperwork, what to do if a case is delayed for any reason, and the proper way to make error corrections. This will all occur by October 5, 2016. 8. Organ staff will be retrained on marking the liver data page appropriately when a biopsy is performed, even if it is not performed locally, as well as the effects of not marking this information appropriately. This will be completed by October 5, 2016. 9. A checklist (has been assigned ORG-098 Case Hand Off Report as an identifier) will be made for Organ Recovery Coordinators to complete at the end of a case in order to communicate to the QA staff any testing that needs [to be] followed up on post case (i.e. pending tests, pending biopsy reports, etc.). The checklist will be implemented no later than October 5, 2016 and staff will be trained on the form. 10. Quality Assurance Coordinators and Organ Recovery Coordinators will be re-trained regarding entry of biopsy results on the anatomy pages in the OPO EMR to ensure correct information is imported into the DDR. Retraining will be completed with appropriate staff no later than October 5, 2016. 11. The QA process for verifying serology results in UNET/TIEDI will be

		updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016. 12. These changes will be reflected in [the OPO's] work instruction WI-QS-009 Completing the Deceased Donor Registration and WI-ORG-068 Organ Chart QA Process. Additionally, the places to look in the donor record for certain information will be added to the WI-QS-009 to ensure that all locations for information have been checked prior to DDR validation. This will be implemented no later than October 5, 2016. 13. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 004 'Organ Donor Suitability & Positive Serologies' will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart on cases where organ and tissue was recovered. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance. The corrective action process will be followed for any non-conformances identified."
Accuracy of Donor Summaries	2 of 5 summaries with errors.	"Root cause: Lack of alignment of processes for Organ department staff entering and validating DonorNet Summaries and Quality Services staff performing quality control of the donor record. No hierarchy of priority of information to be documented. Corrective Action Plan and Estimated Completion Dates: 1. WI-FS-008 Referral process will be updated to reflect that the FSC or ORC who performs the first onsite for the referral will verify the date/time of admission per the hospital face sheet and ensure that the documentation in the OPO EMR is correct. The work instruction will be updated and all FSCs and ORCs trained on the changes no later than October 5, 2016. 2. The Anti-HTLV I/II result was updated to Negative in the DDR on September 18, 2016. We are unable to change the medical-social history comments within UNET. 3. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this

		will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016. 4. These changes will be reflected in [the OPO's] work instruction WI-QS-009 Completing the Deceased Donor Registration. This will be implemented no later than October 5, 2016. 5. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016. 6. A report will be created enabling Quality Assurance staff to monitor the tests that are pending for both organ and tissue cases so that they can obtain tests and ensure compliance. This will be implemented no later than October 13, 2016. 7. WI-QS-009 Completing the Deceased Donor Registration will be updated to explain 'what should be done if the information in the hospital chart differs from what the historian reports in the UDRAI. The updates will be completed and Quality Assurance Coordinators and Organ Recovery Coordinators will be trained on the updates by October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 004 'Organ Donor Suitability & Positive Serologies' will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified."
OPTN Policy 18.1, Table 18-1 requires that OPO submit DDRs within 30 days of form generation	The OPO submitted 7 of 338 (2%) late DDR submissions during the review time period	"During the time period specified, the manner in which DDRs are completed was updated but there was a lot of confusion among coordinators on how to do this and who was responsible for completing the DDR in a timely manner. Who was responsible for the completion of the DDR was not being formally tracked or enforced in any way. Because of volume and process changes, some of the DDRs were completed outside of the 30-day window specified. Root Cause: Lack of alignment of processes for Organ department staff entering and validating DonorNet Summaries and Quality Services staff performing quality control of the donor record. Corrective Action Plan and Estimated Completion Dates: 1. At the conclusion of a case, the Organ Recovery Coordinators are to complete the DDR Entry and Summary page in the electronic medical record system. When the Feedback document is completed in UNET by the Clinical QA Coordinator or Quality Coordinator, they will assign a task in the

		electronic medical record for the final two Organ Recovery Coordinators on the case to complete any of the DDR Entry and Summary page that has not yet been completed. The ORCs will have 10 calendar days to complete this task. Once the task is marked as complete in the EMR, it will send an email to the quality staff who assigned the task stating that the task has been closed. This will alert the quality staff that the DDR is ready to be Reviewed and validated. 2. Policy ORG-C6.000 Data Submission, WI-QS-009 Completing the Deceased Donor Registration, and WI-QS-010 Completing the Donor Organ Disposition will all be updated to reflect the changes outlined above. These updates will be effective no later than October 5, 2016. 3. All Organ Services staff, Quality Assurance Coordinators and Quality Coordinators will be trained on these changes prior to implementation and no later than October 5, 2016. 4. A report will be created that is sent daily to the Manager, Business Analytics & Regulatory Compliance showing pending Feedback, PTRs, and DDR information. Pending reports that are due within 10 days will be highlighted and the Manager, Business Analytics & Regulatory Compliance will be responsible for ensuring reports are completed on time. This update will be effective no later than October 13, 2016."
OPTN Policy 1.2 defines an eligible donor	2 of 2 donors submitted as non eligible should have been reported as Eligible	"The Manager, Organ Services had recently assumed the responsibility of classifying referrals as an 'eligible death' and mistakenly classified these two referrals incorrectly. Additionally, there was not a system to check the accuracy of the classification; the accuracy of information reported was dependent upon one person making the determination by themselves. Root Cause: Lack of training and lack of a QA process. Corrective Action Plan and Estimated Completion Dates: 1. The OPO donor records for [redacted] and [redacted] have been updated to reflect that they were both eligible donors. Death Notification Records were created in UNET for [redacted] and [redacted] on September 14, 2016. 2. The Manager, Organ Services or designee will be required to determine referral classification no less than once per week and a designated Quality team member will be required to review the referral classifications of the Manager, Organ Services or designee no less than once per week. These individuals will be required to discuss referral classification in the event of a disagreement. These changes will be implemented no later than October 5, 2016. 3. The Manager, Organ Services or designee will indicate the referral classification in the electronic medical record system. A designated Quality team member will write 'Verified' upon verification and agreement with Manager, Organ Services' referral classification in the appropriate comments

		section in the electronic medical record system, which will signify review of the eligibility criteria. These changes will be implemented no later than October 5, 2016. 4. Policy ORG C6.000 Data Submission will be updated to reflect that the Manager, Organ Services or designee and a member of the Quality team will make the determination of 'eligible death' together prior to that information being entered into UNET. The policy update will become effective no later than October 5, 2016. 5. The Manager, Organ Services and the Quality staff will be trained on these changes prior to implementation and no later than October 5, 2016. Effectiveness assessment: By the tenth of the month, the preceding month's brain deaths and eligibility classifications will be audited by the COO or CEO or designee to ensure compliance with the process."

Link to Audit Report

Link to CAP

Link to SBAR

Link to CMS Report

OPO 34451L
Date of Review: August 30-31, 2016
Review Period: July 1, 2014 – July 1, 2016

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The United Network for Organ Sharing (UNOS) has a contract with the Health Resources and Services Administration (HRSA), Department of Health and Human Services, to administer the Organ Procurement and Transplantation (OPTN) Network. One requirement of this contract is that UNOS conduct reviews of member organizations' compliance with OPTN requirements. OPTN requirements include National Organ Transplant Act (NOTA), [as amended, 42 U.S.C. 273 et seq], OPTN Final Rule, [42 CFR Part 121], and OPTN Policies and Bylaws.

According to Title 42, Part 121 of the Code of Federal Regulations (CFR), the OPTN shall conduct "ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies."

UNOS conducted a routine on-site survey of OPO 34451L on August 30-31, 2016 .

PROGRAM BACKGROUND

OPO 34451L was approved for membership with UNOS on September 28, 1987, and remains a member in good standing. UNOS staff notified the administrative director that an on-site survey would take place. UNOS staff scheduled the review and confirmed this date in writing on June 30, 2016. A list of donor records that UNOS site surveyors requested to review was provided on July 27, 2016.

REVIEW METHODOLOGY

The following methods were used in this survey of compliance with OPTN requirements:

1. A sample of donor records, and any material incorporated into the donor record by reference, was reviewed to verify the accuracy of OPTN-required data reported to UNOS.
2. A sample of donor records, and any material incorporated into the donor record by reference, was reviewed to verify that transplant-related activities are carried out in a manner consistent with OPTN requirements.
3. OPO internal policies and procedures were reviewed to determine compliance with OPTN requirements.
4. OPO staff interviews to validate OPO policies and protocols.

INTRODUCTION

The following report outlines the compliance results for the OPO in the following areas:

I. Donor Record Review
   - A. Critical data review including accuracy of serology and HLA results
   - B. OPTN Policy review
   - C. Data validation
   - D. Priority UNOS Member Quality Management Review

II. Policy Review and Process Validation

III. Data Submission
   - A. Deceased donor registration forms
   - B. Donor organ disposition (feedback)

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C. Potential transplant recipient refusal codes

IV. Monthly Death Notification Information

A complete copy of OPTN policies can be found at http://optn.transplant.hrsa.gov.

I. Donor Record Review

A. Critical data review – donors in Attachment 1 – 30 donor records

This portion of the audit report summarizes compliance with OPTN Policies and accuracy of information submitted in UNet[SM].

- OPTN Policy 2.2 OPO Responsibilities, pronouncement of death
- OPTN Policy 2.2 OPO Responsibilities, authorization for donation
- OPTN Policy 2.2 OPO Responsibilities, accuracy of serology test results recorded in donor file
- OPTN Policy 2.6.B Deceased Donor Blood Subtype Determination
- Accuracy of Human Leukocyte Antigen (HLA) test results entered in UNet[SM]

Critical data review for donors in Attachment 1

30 records reviewed (20 reviewed on Attachment 1a, 12 reviewed on Attachment 1c [2 records on Attachment 1a were also reviewed on Attachment 1c])
3 records unverified
2 of 20 records noncompliant with OPTN Policy 2.2 (pronouncement of death)
2 of 20 records unverified for serology results

The following donor record did not have documentation verifying that death is pronounced according to applicable laws as required by OPTN Policy 2.2 #5:

- [redacted] – Death pronouncement by physician not included in the donor record. (Pronouncement made by Nurse Practitioner without physician signature.) Documentation of clinical exam consistent with brain death not included in the donor record. Upon request, clinical exam provided by OPO reports patient with "minimal gag reflex" intact.
- [redacted] – Documentation of a clinical exam consistent with brain death not included in the donor record and could not be produced by the OPO upon request.

Donor ID	UNet[SM] documentation	Donor Record documentation
[redacted]	HTLV = Not Done	HTLV = Negative
[redacted]	EBV IgG = Negative EBV IgM = Positive	EBV IgG = Positive EBV IgM = Negative

Requested action: Please provide a corrective action plan to ensure accurate data entry and compliance with OPTN Policy 2.2, pronouncement of death and accuracy of serology results recorded in donor file.

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B. OPTN Policy review of donors in Attachment 2 - 21 donor records

- OPTN Policy 2 Deceased Donor Organ Procurement
- OPTN Policy 15.4.B Requirements for Living donor Recovery Hospital and Host OPOs
- OPTN Policy 16.5 (previously OPTN Policy 16.6 prior to June 23, 2016) Verification of Information before Shipping

Policy review for donors in Attachment 2

21 records reviewed
8 of 21 noncompliant with OPTN Policy 2.0
10 of 21 noncompliant with OPTN Policy 16.6 (06/23/16: OPTN Policy 16.5)

The following donor record did not have documentation of a confirmatory test for brain death in the donor record as required by OPTN Policy 2.2 (pronouncement of death).

- [redacted] (Apnea test was aborted due to donor instability)

The following donor records did not have donor record documentation of an archived sample as required by OPTN Policy 2.2:

- [redacted] (lab contacted for documentation)
- [redacted]

The following donor records did not have a properly documented hemodilution calculation for serological testing as required by OPTN Policy 2.5:

- [redacted]
- [redacted]
- [redacted]

The following donor record did not have documentation of urinalysis within 24 hours of cross clamp as required by OPTN Policy 2.8:

- [redacted]

The following donor records did not have documentation of flush solution and/or additive lot numbers as required by OPTN Policy 2.15.C (previously OPTN Policy 2.15.B):

- [redacted] (Prostin)
- [redacted] (Viaspan, Perfadex, Plasmalyte)
- [redacted] (Viaspan)

The following donor records contained a generic statement signed by two individuals stating that all organs and vessels were packaged and verified in accordance with OPTN Policy 5.0. This generic statement did not cite current policy at time of procurement as required by OPTN Policy 16.5 (previously OPTN Policy 16.6):

- [redacted]
- [redacted]
- [redacted]

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- [redacted]

The following donor record did not have documentation of two individuals verifying organ and vessel packaging and labeling at the same time as required by OPTN Policy 16.5 (previously OPTN Policy 16.6). Cross clamp was 4/20/16 - 0309. First verifier signed the generic form on 4/20/16 – 0405. Second verifier signed the form on 4/22/16 – 1313.

- ADDR092

Requested action: Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15.C (previously 2.15.B), and 16.5 (previously OPTN Policy 16.6).

C. Data Validation - donors in Attachment 3 – 5 donor records

Validation of data submitted in Tiedi® for Deceased Donor Registration forms for donors in Attachment 3

5 DDR forms reviewed
4 DDR forms with errors
13 total number of errors

Donor ID	Tiedi® documentation	Donor record documentation
[redacted]	**Organ Recovery:** Chest X-ray = Abnormal – left	**Organ Recovery:** Chest X-ray = Abnormal – both
[redacted]	**Organ Recovery:** Date and Time agonal phase begins (systolic BP < 80 or O2 sat. < 80%): 04/17/2016 – 12:12 The OPO did not provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death.	**Organ Recovery:** Date and Time agonal phase begins (systolic BP < 80 or O2 sat. < 80%): 04/17/2016 – 12:16 The OPO had data available through 12:22 in the donor record. Time of death is 04/17/2016 – 12:25.
[redacted]	**Procurement and Authorization:** Date and time authorization obtained for organ donation: 04/18/2016 – 14:39 **Donor Management:** (Any medications administered within 24 hours prior to cross	**Procurement and Authorization:** Date and time authorization obtained for organ donation: Unable to verify. (time) **Donor Management**: (Any medications administered within 24 hours prior to cross

	clamp.) Other/Specify: No medications listed. **Organ Recovery:** The OPO did not provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death. Liver Biopsy: No	clamp.) Other/Specify: Keppra **Organ Recovery:** The OPO had data available through 01:04 in the donor record. Time of death is 04/20/2016 – 01:08. Liver Biopsy: Yes, received biopsy report from the transplant center on 05/03/2016.
[redacted]	**Clinical Information:** Serology: HTLV Serology Results: Not Done West Nile Serology Results: Negative West Nile NAT Results: Not Done **Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Diuretics: No Arginine Vasopressin: No Inotropic Medications at Time of Cross Clamp: No	**Clinical Information:** Serology: HTLV Serology Results: Negative West Nile Serology Results: Not Done West Nile NAT Results: Negative **Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Diuretics: Yes, Mannitol given in the OR Arginine Vasopressin: Yes Inotropic Medications at Time of Cross Clamp: Yes, Levophed running at cross clamp per anesthesia record.

Requested action: Please make corrections in Tiedi® on these DDRs and submit a corrective action plan to ensure that similar errors do not occur in the future.

Validation of data submitted for Donor Summaries in Attachment 3

5 donor summaries were reviewed
2 of 5 summaries with errors

Donor ID	DonorNet® documentation	Donor record documentation
[redacted]	**Donor Information:** Admit Date: 02/11/2016 - 01:00	**Donor Information:** Admit Date: 02/11/2016 – 02:19
[redacted]	**Medical and Social History:** History of hypertension, compliant with treatment: Yes **Medical and social history comments:** "Patient did have HTN for the past 5 or 6 years and was on medications for control. "	**Medical and Social History:** History of hypertension, compliant with treatment: Unable to verify **Medical and social history comments:** Per mother on DRAI, the donor "never took medication for it."

	Infectious Diseases: Anti-HTLV I/II: Not Done	**Infectious Diseases:** Anti-HTLV I/II: Negative

Requested action: Please provide a corrective action plan that shows how the OPO will ensure the accuracy of data entered into DonorNet®.

D. Priority UNOS Member Quality Management Review

During on-site donor record review, UNOS identified potential policy violations that warranted priority review by Member Quality management. Site surveyors noted irregularities in brain death pronouncement documentation retained for OPO records. Six donor records were missing one of the following elements: clinical exam showing absence of all brainstem reflexes, confirmatory test in lieu of aborted apnea tests (donor instability), or brain death pronouncement note signed by an attending physician.

Site surveyors requested additional documentation to demonstrate compliance with OPTN Policy. After several hours and contact with donor hospitals, the OPO produced the appropriate documentation for three of these records. The remaining three unverified records are cited in this report under Attachments 1 and 2.

UNOS requested that the OPO come into immediate compliance and the OPO provided a containment plan prior to the conclusion of the on-site audit. Due to the potential threat to the integrity of the OPTN presented by the potential policy violations, Member Quality management determined that the Membership and Professional Standards Committee (MPSC) and Human Resources and Services Administration (HRSA) must be made aware of the findings of this review. In addition, this survey has been placed on an expedited pathway for review at the MSPC Meeting in October. As a result, Member Quality management will be requiring the OPO to provide a corrective action plan, as well as additional information requested by the MPSC included with this report, by **September 27, 2016**.

II. Policy Review and Process Validation

UNOS Site Surveyors reviewed the OPO's internal policies and procedures and interviewed relevant OPO staff to determine that they contained the following elements in compliance with OPTN policies:

a. OPTN Policy 2.6 Deceased Donor Blood Type Determination and Reporting

The OPO submitted the following internal policies, procedures and/or protocols to UNOS for review: • Title: ABO Confirmation, Department: ORG, Section: A, Policy: 17.000, Revision: 11, Effective Date 02/01/2016
As part of the survey process, OPO protocols/policies were reviewed to verify compliance with OPTN

Policies. The findings of this review are as follows:	
Required Element	**Element in Protocol**
Tests were completed using two separate blood samples	Verified
Protocol to resolve conflicting primary blood types	Verified
Verification that two individuals performing blood type reporting each consulted source documents	Verified
Verification occurs prior to the match run *or* In cases of accelerated donation, verification occurs *prior* to organ release to the transplant hospital	Unable to verify, accelerated donation element is not present.

During the onsite review, site surveyors conducted an interview with two Organ Recovery Coordinators (ORCs) about how they perform ABO verification. Site surveyors validated that OPO staff practices align with the OPO's policies and procedures related to OPTN Policy 2.6.

Requested action: **Please provide a corrective action plan to ensure compliance with OPTN Policy 2.6.**

b. **OPTN Policy 2.6.B Deceased Donor Blood Subtype Determination**

The OPO submitted the following internal policies, procedures and/or protocols to UNOS for review:

- Title: ABO Confirmation, Department: ORG, Section: A, Policy: 17.000, Revision: 11, Effective Date 02/01/2016

As part of the survey process, OPO protocols/policies were reviewed to verify compliance with OPTN Policies. The findings of this review are as follows:

Required Element	**Element in Protocol**
Tests were completed using two separate blood samples	Verified
Samples used were pre red blood cell transfusion	Unable to verify
If conflicting subtype results, the subtype must not be reported	Verified

During the onsite review, site surveyors conducted an interview with two Organ Recovery Coordinators (ORCs) about their knowledge regarding the process for subtyping of blood group A donors. Based on staff interviews, there was a knowledge gap regarding the content of the OPO's Policy 17.000, Revision: 11 and the OPO's staff practices.

During the interviews, it was determined that staff were inconsistent in verbalizing the requirement for pre red blood cell transfusion samples in subtyping, confusing pre-transfusion with hemodilution.

Requested action: Please provide a corrective action plan to ensure compliance with OPTN Policy 2.6.B.

c. OPTN policies 1.2 Definitions and 2.15.B Pre-Recovery Verification

The OPO submitted the following internal policies, procedures and/or protocols to UNOS for review:

- Title: ABO Confirmation, Department: ORG, Section: A, Policy: 17.000, Revision: 11, Effective Date 02/01/2016
- ABO Verification Form, ORG-042-12, Effective Date: 06/23/16

As part of the survey process, OPO protocols/policies were reviewed to verify compliance with OPTN Policies. The OPO's policy contained all required elements:

Required Element	Element in Protocol
Definition of qualified healthcare professional	Verified
Verification of: ○ **Donor ID** ○ **Organ** ○ **Organ laterality (if applicable** ○ **Donor blood type** ○ **Donor subtype (if used for allocation)** **Verified by the recovering surgeon and one qualified healthcare professional**	Verified
If the recipient is known ○ **Intended recipient unique ID** ○ **Intended recipient blood type** **Donor and intended recipient are compatible or intended incompatible** **Verified by two qualified healthcare professionals using the OPTN computer system**	Verified

During the onsite review, site surveyors conducted an interview with two Organ Recovery Coordinators (ORCs) about their knowledge regarding the process for performing a pre-recovery verification. Site surveyors validated that OPO staff practices align with the OPO's policies and procedures related to OPTN Policy 2.15.B.

III. Data Submission

Effective February 1, 2014, UNOS reviews an OPO's compliance with the requirements for data submission as listed in OPTN Policy 18.1 and Table 18-1.

A. Deceased Donor Registration (DDRs) forms

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OPO 34451L had the following late DDR submissions between July 1, 2014 – July 1, 2016. There were 7 of 338 (2%) late DDR submissions during this time period. See below for details.

Donor ID	Last Name	First Name	Date Donor Added	DDR Expected Date	Date DDR First Validated	Days Overdue
[redacted]			15NOV2014	18DEC2014	19DEC2014	1
[redacted]			11FEB2016	15MAR2016	20MAR2016	5
[redacted]			11FEB2016	15MAR2016	20MAR2016	5
[redacted]			12FEB2016	17MAR2016	20MAR2016	3
[redacted]			13FEB2016	18MAR2016	21MAR2016	3
[redacted]			01APR2016	06MAY2016	07MAY2016	1
[redacted]			03APR2016	06MAY2016	07MAY2016	1

DDR forms must be submitted within 30 days as required by Policy 18.1, Table 18-1 (previously OPTN Policy 7.2).

Requested action: Please submit a corrective action plan to ensure that DDR forms will be submitted within the required thirty days as required by Policy 18.1 (previously Policy 7.2).

B. Donor organ disposition (feedback)

OPO 34451L had no late donor feedback submissions between July 1, 2014 – July 1, 2016.

C. Potential Transplant Recipient (PTRs) refusal codes

OPO 34451L had no overdue Potential Transplant Recipient (PTR) refusal codes between July 1, 2014 – July 1, 2016.

IV. Monthly Death Notification Information

UNOS reviewed the OPO's methodology for reporting monthly death notification information in UNet^{SM}.
Two donor records were reviewed to determine the accuracy of the OPO's use of the definition of an "Eligible Death" as defined in OPTN Policy 1.2. The number of donor records included all brain dead non-eligible donors < 71 years old.

The review identified two donors the OPO should have reported as Eligible.

- [redacted]
- [redacted]

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Requested action: Please complete a Death Notification Record (DNR) for each incorrectly reported donor and provide a corrective action plan detailing how the OPO will ensure compliance in reporting an eligible death as defined in OPTN Policy 1.2.

Membership and Professional Standards Committee
Additional Information Request

1) Provide OPO policies relative to documentation of brain death and obtaining required source documents.
2) Provide the OPO's pertinent staff training program and documentation relative to organ recovery staff assuring brain death has been properly declared and documented per OPO policy, as well as copies of the pertinent training documentation for staff involved in the three cases in question.
3) Clarify the role of the Medical Director in the above as well as in addressing identified issues in real time.
4) Provide OPO quality policies, processes, and pertinent documentation for reviewing donor records to assure brain death declaration has been appropriately documented in the permanent donor record, and any policies for internal and external reporting of occurrences when issues are identified.
5) Provide any documentation of review, occurrences, or corrective action by either operations or quality leadership relative to these three cases, or any brain death related occurrences in the last 12 months.
6) Conduct and provide results of a look back internal audit reviewing and verifying brain death documentation on 100% of recovered brain dead donors from the donor hospitals involved in these three cases for the last 12 months.
7) Provide copies of hospital policies for organ donation for the hospitals involved in the three cases in question.
8) Provide any documentation of follow-up with the donor hospitals involved in these three cases since completion of the UNOS site survey.
9) Provide documentation of current staffing model for Quality and Organ Departments including reporting structure and allocation of staffing resources (full and part-time employees).

Requested Action: Please provide the information requested above, along with your report response and Corrective Action Plan, by **September 27, 2016.**

[redacted]

September 27, 2016

UNOS Member Quality
Attention: [redacted]
700 North 4th Street
Richmond, Virginia 23219

RE: [redacted] on-site review

Dear [redacted]:

I am writing in regards to the on-site review at [redacted] on August 30-31, 2016, which was conducted by UNOS' Member Quality. We have reviewed and completed a full analysis of violations of OPTN Policies 1.2, 2.2, 2.5, 2.6, 2.15.C (previously OPTN Policy 2.15.B), 16.5 (previously OPTN Policy 16.6), and 18.1. We also reviewed the accuracy of information submitted on the Deceased Donor Registration (DDR) forms. The enclosed UNOS Report Responses and Corrective Action Plans provide explanations of the nonconformances identified and the corrective actions to be taken by [redacted]

In addition to the Corrective Action Plans provided, [redacted] will be reviewing our entire QAPI program with the assistance of consultants to ensure a full program is in place to identify, correct, and track nonconformances as well as to derive data that will be utilized to monitor and improve our performance. As part of our corrective action process, the [redacted] reached out to its peers at the [redacted] to review how each of these OPOs ensure appropriate brain death declaration and documentation.

At [redacted] we feel passionately about performance and continually strive to meet all regulatory requirements. We have put significant energy into examining not only the human factors in the errors identified, but also the integrity of procedures employed throughout the organization. We understand that we have some systemic issues and we also understand the severity of all violations identified, including brain death pronouncement documentation which has been escalated to Membership and Professional Standards Committee (MPSC) and Human Resources and Services Administration (HRSA).

We appreciate the UNOS Member Quality's review, which ensures [redacted]s full compliance with OPTN policies and upholds the integrity of organ donation and transplantation. If you have any questions or need any additional information, please contact me at [redacted] or [redacted].

Sincerely,

[redacted]
President/CEO

[redacted]

[redacted] **Corrective Action Plan** **Provided to OPTN/UNOS for the** **UNOS Site Survey August 30-31, 2016**	
Section I - Donor Record Review	**A. Critical Data Review**
Area of Non-Compliance #1	The following donor records did not have documentation verifying that death is pronounced according to applicable laws as required by OPTN Policy 2.2 #5: • [redacted] – Death pronouncement by physician not included in the donor record. (Pronouncement made by Nurse Practitioner without physician signature.) Documentation of clinical exam consistent with brain death not included in the donor record. Upon request, clinical exam provided by OPO reports patient with "minimal gag reflex" intact. • [redacted] – Documentation of a clinical exam consistent with brain death not included in the donor record and could not be produced by OPO upon request.
Requested Action(s)	Please provide a corrective action plan to ensure accurate data entry and compliance with OPTN Policy 2.2, pronouncement of death and accuracy of serology results recorded in donor file.
Explanations	[redacted] law does not exist as to how brain death declaration must occur nor is [redacted] aware of any federal laws or statutes that exist in regards to how brain death declaration is to be performed in [redacted] While there are guidelines for determining brain death in [redacted] these are only guidelines and not law. Since its inception, the [redacted] has relied on the hospital expertise only to pronounce brain death. [redacted] Policy FS B3.000 Verification and Documentation of Brain Death and practice has been to ensure a copy of the hospital brain death documentation is obtained and placed in the donor chart. This documentation per policy has been to ensure it includes that the patient is brain dead, the date/time and a signature by a physician. Staff were inconsistently verifying this documentation. [redacted] did not have a process for ensuring the integrity of the brain death process.

	Root cause: Inconsistent verification of documentation and no federal law or state statute defining proper documentation of brain death. Lack of internal process for verifying hospital policy is followed or for ensuring integrity of brain death process.
Corrective Action Plan and Estimated Completion Dates	A containment plan was put into place on August 31, 2016. All Quality, Organ Services, Family Services, and Professional Services staff could not sign into our electronic medical records system until they acknowledged receipt of information regarding the containment plan. The acknowledgement notice stated the following: "1) Moving forward, the Family Services Coordinators (FSCs) will be required to ensure that a negative clinical exam and apnea test are documented in the hospital chart and that a copy is made and placed in the [redacted] chart along with the documentation of brain death pronouncement by a physician. 2) If an NP is documenting the brain death examination, the note must be co-signed by the attending physician that they are working under the direction of. If not co-signed, it cannot be accepted and [redacted] will not proceed with organ recovery until accurate documentation is received from the hospital. This aligns with hospital contract language stating that 'the determination of death for a Potential Donor shall be made by the Donor's attending physician or by the physician responsible for certifying death at the Hospital.' 3) The FSCs and Organ Recovery Coordinators (ORCs) will add to their hand off/report (documented on the Clinical Pathway) that they have reviewed the documentation of the clinical exam, apnea test, and ancillary procedures (if applicable) and that a copy of these items and the death note have been placed in the [redacted] chart. 4) The Clinical Quality Assurance Coordinators will be trained that when reviewing donor charts, documentation of a negative clinical exam and apnea test must be present in the [redacted] chart along with a proper brain death note. Ancillary testing might also be present if performed. Acknowledgement of this notice confirms your understanding of these requirements and indicates your ability to comply with these requirements as stated above. All questions and concerns should immediately be directed to your manager." Please see attached summary of users along with their role and date/time of acknowledgement. This was implemented on August 31, 2016.

The above was a containment plan implemented immediately while Member Quality was onsite on August 31, 2016. Since then, the following corrective actions will supersede this immediate containment plan.

1. An emergency meeting of the [redacted] Advisory Board will be held by October 5, 2016 where the Advisory Board will determine minimum standards as to what must be documented in the hospital's brain death note in order for [redacted] to accept it as a suitable brain death declaration note. This will include that all brain death declarations must be completed by a MD or DO. The [redacted] Chief Medical Officer will also be part of this meeting in determining standards.
2. Policy FS B3.000 Verification and Documentation of Brain Death will be updated by October 9, 2016 to reflect that the [redacted] will follow each individual hospital policy for brain death and that at a minimum the recommendations from the Advisory Board as to brain death documentation must occur. Additional updates to this policy will include:
    - all brain death documentation is uploaded into the appropriate donor case in the "BD Documentation" section of the electronic medical record system.
    - the organ recovery coordinator/family services coordinator must call the administrator on call (AOC) and have the AOC verify that the brain death note documentation matches the hospital policy and at a minimum has the requirements that the Advisory Board recommended.
    - the brain death documentation to be verified by the AOC should be reviewed from the attachments section in the electronic medical records system. This review by the AOC will be documented as a case note in the electronic medical record system.
3. An emergency meeting of the [redacted] Governing Board Executive Committee will be held by October 10, 2016 to approve the recommendations to Policy FS B3.000 Verification and Documentation of Brain Death that was recommended by the Advisory Board. Additionally, the policy will be shared at the next board meeting with all governing board members.
4. Once the policy has been reviewed and approved by the Executive Committee, the Organ Services, Professional Services and Family Services staff will be trained on the policy by October 13, 2016.

5. [redacted] work instruction WI-ORG-068 Organ Chart QA Process will be created to reflect the key elements that need to be verified as it relates to documentation regarding pronouncement of brain death per FS Policy B3.000 Verification and Documentation of Brain Death. This will be implemented and Organ Services, Quality Assurance Coordinators and Family Services Coordinators will be trained no later than October 13, 2016 on WI-ORG-068 Organ Chart QA Process.
6. The [redacted] Professional Services staff will do a 100% review of all organ potential hospital brain death policies by September 28, 2016. Each of the hospital policies on brain death will be uploaded into the iTransplant medical charting system for access by the organ recovery coordinators, family services coordinators, professional services coordinators, quality assurance coordinators and any other applicable staff.
7. In the event that an organ hospital does not have a policy on brain death, the professional services staff or a member of leadership will make contact with the hospital to ensure a brain death policy is created and implemented. This contact will be completed by October 5, 2016 and it will be stressed that a policy needs implemented in the next 60 days.
8. The Organ Services new coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016.
9. Professional Services staff, President/CEO and Chief Medical Officer will provide communication to all organ hospitals regarding the necessity to pronounce brain death according to hospital policy but also in regards to the minimum requirements for pronouncing brain death that the [redacted] Advisory Board recommends and the Executive Committee approves. This will be completed by October 13, 2016.
10. [redacted] form ORG-002 Clinical Pathway will be updated to ensure brain death is documented properly and reviewed by the AOC. The Clinical Pathway will be updated by October 13, 2016, and family services, organ services and quality assurance coordinators will be trained by October 13, 2016.
11. The Organ Services' new coordinator orientation, Family Services' new coordinator orientation, and new Clinical Quality Assurance Coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016.

	Effectiveness assessment: Within the electronic medical record system, there is documentation completed on every case that lists the methods used to pronounce brain death. A report will be built to monitor those fields and ensure that the proper methods are being utilized to pronounce brain death. The report will be run daily and emailed to the Managers of Family Services and Organ Services so that they can ensure the information is correct and present in the chart. If documentation is not present they will follow up with the appropriate staff immediately. This will be implemented by October 13, 2016. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee, will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #2	2 of 20 records unverified for serology results **Donor ID** | **Tiedi documentation** | **Donor record documentation** [redacted] | HTLV = Not Done | HTLV = Negative

	[redacted]	EBV IgG = Negative EBV IgM = Positive	EBV IgG = Positive EBV IgM = Negative	
Requested Action(s)	Please provide a corrective action plan to ensure accurate data entry and compliance with OPTN Policy 2.2, pronouncement of death and accuracy of serology results recorded in donor file.			
Explanation	[redacted] HTLV is a serology that is not routinely run by our organization on organ donor cases, but is completed on select tissue donor cases at the request of certain tissue processors. The test is ordered/added to the testing panel by the tissue Team Leaders after tissue has been recovered. The results can take up to 5-7 days to receive. Previously, the addition of the HTLV test was not communicated between tissue and the organ Clinical QA Coordinators (the organ chart is looked at separately from the tissue chart and by different coordinators); therefore, the coordinator completing the DDR may not have been aware of an HTLV result needing to be corrected within the DDR. [redacted] The coordinator transposed the results when they were entered into Tiedi. When this occurred we were utilizing the [redacted] electronic medical record system. The results had to be manually entered into Tiedi. We now utilize the Transplant Connect/iTransplant electronic medical record system and the DDR is completed through an import of information pulled from iTransplant into Tiedi. Lack of process for verifying documentation. <u>Root cause</u>: Lack of a verification process resulting in a lack of communication.			
Corrective Action Plan and Estimated Completion Dates	1. Serology results were corrected in Tiedi on September 15, 2016. 2. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016.			

3. On shared organ and tissue cases, a QA team member will share HTLV results with the organ transplant programs. This is current practice and will remain part of the continuing process.
4. These changes will be reflected in [redacted] work instruction WI-QS-009 Completing the Deceased Donor Registration. This will be implemented no later than October 5, 2016.
5. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016.
6. A report will be created enabling Quality Assurance staff to monitor the tests that are pending for both organ and tissue cases so that they can follow up on obtaining results. This will be implemented no later than October 13, 2016.
7. [redacted] Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to require a review of serologies entered into the EMR by the AOC. These forms will be updated by October 5, 2016, and family services, organ services and quality assurance coordinators will be trained by October 5, 2016.

Effectiveness Assessment:
Compliance will be measured through our internal audit process. Internal audit 004 "Organ Donor Suitability & Positive Serologies" will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart on cases where organ and tissue was recovered. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified.

The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion

	and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
	B. OPTN Policy Review
Area of Non-Compliance #3	The following donor record did not have documentation of a confirmatory test for brain death in the donor record as required by OPTN Policy 2.2 (pronouncement of death). • [redacted] (Apnea test was aborted due to donor instability)
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	[redacted] law does not exist as to how brain death declaration must occur nor is [redacted] aware of any federal laws or statutes that exist in regards to how brain death declaration is to be performed in [redacted] While there are guidelines for determining brain death in [redacted], these are only guidelines and not law. Since its inception, the [redacted] has relied on the hospital expertise only, to pronounce brain death. [redacted] policy and practice has been to ensure a copy of the hospital brain death documentation is obtained and placed in the donor chart. This documentation per policy has been to ensure it includes that the patient is brain dead, the date/time and a signature by a physician. Staff were inconsistently verifying this documentation. [redacted] did not have a process for ensuring the integrity of the brain death process. Root cause: Inconsistent verification of documentation and no federal law or state statute defining proper documentation of brain death. Lack of internal process for verifying hospital policy is followed or for ensuring integrity of brain death process.

Corrective Action Plan and Estimated Completion Dates	A containment plan was put into place on August 31, 2016. All Quality, Organ Services, Family Services, and Professional Services staff could not sign into our electronic medical records system until they acknowledged receipt of information regarding the containment plan. The acknowledgement notice stated the following: "1) Moving forward, the Family Services Coordinators (FSCs) will be required to ensure that a negative clinical exam and apnea test are documented in the hospital chart and that a copy is made and placed in the [redacted] chart along with the documentation of brain death pronouncement by a physician. 2) If an NP is documenting the brain death examination, the note must be co-signed by the attending physician that they are working under the direction of. If not co-signed, it cannot be accepted and [redacted] will not proceed with organ recovery until accurate documentation is received from the hospital. This aligns with hospital contract language stating that 'the determination of death for a Potential Donor shall be made by the Donor's attending physician or by the physician responsible for certifying death at the Hospital.' 3) The FSCs and Organ Recovery Coordinators (ORCs) will add to their hand off/report (documented on the Clinical Pathway) that they have reviewed the documentation of the clinical exam, apnea test, and ancillary procedures (if applicable) and that a copy of these items and the death note have been placed in the [redacted] chart. 4) The Clinical Quality Assurance Coordinators will be trained that when reviewing donor charts, documentation of a negative clinical exam and apnea test must be present in the [redacted] chart along with a proper brain death note. Ancillary testing might also be present if performed. Acknowledgement of this notice confirms your understanding of these requirements and indicates your ability to comply with these requirements as stated above. All questions and concerns should immediately be directed to your manager." Please see attached summary of users along with their role and date/time of acknowledgement. The implementation date was August 31, 2016. The above was a containment plan implemented immediately while Member Quality was onsite on August 31, 2016. Since then, the following corrective actions will supersede this immediate containment plan.

1. An emergency meeting of the [redacted] Advisory Board will be held by October 5, 2016 where the Advisory Board will determine minimum standards as to what must be documented in the hospital's brain death note in order for [redacted] to accept it as a suitable brain death declaration note. This will include that all brain death declarations must be completed by a MD or DO. The [redacted] Chief Medical Officer will also be part of this meeting in determining standards.
2. Policy FS B3.000 Verification and Documentation of Brain Death will be updated by October 9, 2016 to reflect that the [redacted] will follow each individual hospital policy for brain death and that at a minimum the recommendations from the Advisory Board as to brain death documentation must occur. Additional updates to this policy will include:
    - all brain death documentation is uploaded into the appropriate donor case in the "BD Documentation" section of the electronic medical record system.
    - the organ recovery coordinator/family services coordinator must call the administrator on call (AOC) and have the AOC verify that the brain death note documentation matches the hospital policy and at a minimum has the requirements that the Advisory Board recommended.
    - the brain death documentation to be verified by the AOC should be reviewed from the attachments section in the electronic medical records system. This review by the AOC will be documented as a case note in the electronic medical record system.
3. An emergency meeting of the [redacted] Governing Board Executive Committee will be held by October 10, 2016 to approve the recommendations to Policy FS B3.000 Verification and Documentation of Brain Death that was recommended by the Advisory Board. Additionally, the policy will be shared at the next board meeting with all governing board members.
4. Once the policy has been reviewed and approved by the Executive Committee, the Organ Services, Professional Services and Family Services staff will be trained on the policy by October 13, 2016.
5. [redacted] work instruction WI-ORG-068 Organ Chart QA Process will be created to reflect the key elements that need to be verified as it relates to documentation regarding pronouncement of brain death per FS Policy B3.000 Verification and Documentation of Brain Death. This will be implemented and Organ

Services, Quality Assurance Coordinators and Family Services Coordinators will be trained no later than October 13, 2016 on WI-ORG-068 Organ Chart QA Process.

6. The [redacted] Professional Services staff will do a 100% review of all organ potential hospital brain death policies by September 28, 2016. Each of the hospital policies on brain death will be uploaded into the iTransplant medical charting system for access by the organ recovery coordinators, family services coordinators, professional services coordinators, quality assurance coordinators and any other applicable staff.
7. In the event that an organ hospital does not have a policy on brain death, the professional services staff or a member of leadership will make contact with the hospital to ensure a brain death policy is created and implemented. This contact will be completed by October 5, 2016 and it will be stressed that a policy needs implemented in the next 60 days.
8. The Organ Services new coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016.
9. Professional Services staff, President/CEO and Chief Medical Officer will provide communication to all organ hospitals regarding the necessity to pronounce brain death according to hospital policy but also in regards to the minimum requirements for pronouncing brain death that the [redacted] Advisory Board recommends and the Executive Committee approves. This will be completed by October 13, 2016.
10. [redacted] form ORG-002 Clinical Pathway will be updated to ensure brain death is documented properly and reviewed by the AOC. The Clinical Pathway will be updated by October 13, 2016, and family services, organ services and quality assurance coordinators will be trained by October 13, 2016.
11. The Organ Services' new coordinator orientation, Family Services' new coordinator orientation, and new Clinical Quality Assurance Coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016.

Effectiveness assessment:
Within the electronic medical records system, there is documentation completed on every case that lists the methods used to pronounce brain death. A report will be built to monitor those fields and ensure that the proper methods are being utilized to pronounce brain death. The report will be run daily and emailed to the Managers of Family Services and Organ

	Services so that they can ensure the information is correct and present in the chart. If documentation is not present they will follow up with the appropriate staff immediately. This will be implemented by October 13, 2016. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #4	The following donor records did not have donor record documentation of an archived sample as required by OPTN Policy 2.2: • [redacted]6 (lab contacted for documentation) • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	This occurred because we did not have any checks within the QA process to ensure that the statement was on the final HLA report received from the lab who archives the serum for us.

	They did produce updated documentation during the audit verifying that there was archived serum available for these two donors. Root cause: Lack of QA process
Corrective Action Plan and Estimated Completion Dates	1. All donor records from August 1, 2015 through current have been checked to ensure that the statement regarding an archive sample is present on the final report received from the lab archiving serum for organ donors. 2. [redacted] work instruction WI-ORG-068 will be created to reflect that all final HLA reports must have the statement "1.5 mL of serum is archived on this donor and will be saved for a minimum of 10 years." If the statement is not present, the lab will be contacted by the Clinical QA Coordinator to find out if there is archive serum at the lab. If there is, an amended report will be requested. If there is no serum archive, a reportable event will be written and the investigation will be completed and documented through the CAPA process. This will be implemented no later than October 5, 2016. 3. The Clinical QA Coordinators will be trained on WI-ORG-068 by October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 015 "Organ Donor Records" will have an audit item added where the auditor will perform a random chart sampling to verify that the statement "1.5 mL of serum is archived on this donor and will be saved for a minimum of 10 years" appears on all final HLA reports sampled. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified. The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in

	this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #5	The following donor records did not have a properly documented hemodilution calculation for serological testing as required by OPTN Policy 2.5: • [redacted] • [redacted] • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	Internal policies and work instructions were not specific enough with regards to how the hemodilution needs to be completed. Specific information was outlined regarding blood products and colloids, but little guidance was given in regards to documenting crystalloids; therefore, documentation was inconsistent from one coordinator to another. Proper education for the Organ Recovery Coordinators related to the hemodilution calculation, specifically when crystalloids were a factor, was lacking. <u>Root cause:</u> Lack of training and competency.
Corrective Action Plan and Estimated Completion Dates	1. [redacted] forms ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the blood bank needs to be contacted prior to completing the hemodilution on all cases to confirm the amount of blood products released/administered to the patient. If available, the blood administration records

must be copied and placed in the donor record. If not available, it must be documented why they could not be obtained. This will also be updated in policy ORG A8.000 Serology Hemodilution Qualification. These updates will be made no later than October 5, 2016.

2. All Organ Services staff and Clinical Quality Assurance Coordinators will be trained on the policy and form updates prior to implementation and no later than October 5, 2016.
3. The Organ Services and Quality Assurance staff will be retrained on the hemodilution calculation. This education will include the rationale for performing the hemodilution, the components of the hemodilution (blood products, colloids, and crystalloids) and how they affect the sample, how to properly document the hemodilution, and what to do if the sample is found to be hemodiluted. There will also be a test to assess knowledge and understanding of the material presented. All staff will need to pass the test/assessment with 100%. This will be complete by all staff affected no later than October 5, 2016.
4. The Organ Services and Quality Assurance staff will be tested on hemodilution concepts, at a minimum, annually, once being released from orientation. The orientation training over hemodilution will also be assessed and updated to include what is outlined above and will be implemented no later than October 5, 2016.

Effectiveness assessment:
The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends

	are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #6	The following donor record did not have documentation of urinalysis within 24 hours of cross clamp as required by OPTN Policy 2.8: • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	A urinalysis was conducted within 24 hours of cross clamp, but the results were not documented in the electronic medical record and were thus not available at the time of inspection to the inspectors. <u>Root cause:</u> Lack of verification process for ensuring that tests that were performed without results being received prior to the OR were obtained after procurement.
Corrective Action Plan and Estimated Completion Dates	1. The urinalysis results were obtained from the donor hospital and documented in the donor record (please see attached copy). 2. A checklist (has been assigned ORG-098 Case Hand Off Report as an identifier) will be made for Organ Recovery Coordinators to complete at the end of a case in order to communicate to the QA staff any testing that needs followed up on post case (i.e. pending tests, pending biopsy reports, etc.). The checklist will be implemented no later than October 5, 2016. 3. The checklist will be added to [redacted] policy ORG C1.000 Local Donor Chart Documentation and Completion. The policy will be updated and effective no later than October 5, 2016. 4. [redacted] form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that prior to entering the OR, the ORC must verify that a urinalysis with micro was performed within 24 hours of when cross clamp is expected to occur. If one has not been performed that will meet this timeframe, a

urinalysis with micro will be ordered. These forms will be updated and effective no later than October 5, 2016.

5. [redacted] Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm urinalysis results of no more than 24 hours prior to entering OR are in the EMR. These forms will be updated and effective no later than October 5, 2016.
6. An automated report will be created and sent to QA weekly that lists the donors from the week, cross clamp date and time, and date and time of the latest U/A documented in the OPO EMR. This will be reviewed by the Manager, Business Analytics and Regulatory Compliance with the QA team to ensure compliance. This will be implemented no later than October 13, 2016.
7. All Organ Services and Quality Assurance Coordinators will be trained on the new form, the updated clinical pathways, and policy updates no later than October 5, 2016.

Effectiveness assessment:
The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

	The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #7	The following donor records did not have documentation of flush solution and/or additive lot numbers as required by OPTN Policy 2.15.C (previously OPTN Policy 2.15.B): • [redacted] (Prostin) • [redacted] (Viaspan, Perfadex, Plasmalyte) • [redacted]6 (Viaspan)
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	The solutions and/or additives were for products brought into the OR by either out-of-state centers or the local thoracic teams. The [redacted] Organ Recovery Coordinators failed to remember to obtain the necessary information and when the transplant centers were contacted they did not have record of the information needed. For abdominal recoveries performed by our local transplant centers, this information is captured in our inventory system. For all other recoveries we rely on the Organ Recovery Coordinators to remember to obtain the information from the other transplant centers involved, but there is no visual reminder currently. <u>Root cause:</u> Lack of appropriate forms, processes, and accountability measures.
Corrective Action Plan and Estimated Completion Dates	1. The Verification of Donor Information form (ORG-063) will be updated to include fields to document the solutions, additives, lot number and expiration dates of the items used in the recovery of the organs. This will be implemented no later than October 5, 2016. 2. [redacted] Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm fields to document the solutions, additives, lot number and expiration dates of the items used in the recovery of organs have been completed on ORG-063. These forms will be updated and effective no later than October 5, 2016. 3. Policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs will be updated to reflect where the lot and expiration information will be captured for all solutions and additives used in the OR by out-of-state centers and local thoracic transplant centers. This will be implemented no later than October 5, 2016.

4. All ORC staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates as well as the importance of documenting this information no later than October 5, 2016.

Effectiveness assessment:
Internal audit 007 Organ Donor Management, Allocation, and Recovery contains an item where the lot/expiration information needs to be verified in a random sampling of charts. This item will be updated to include that the random sampling of charts must include cases where either out-of-state recovery teams or local thoracic teams were involved in the recovery of organs will be checked to verify that all lot and expiration information is present for the solutions/additives used in the OR. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified.

The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

	The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #8	The following donor records contained a generic statement signed by two individuals stating that all organs and vessels were packaged and verified in accordance with OPTN Policy 5.0. This generic statement did not cite current policy at time of procurement as required by OPTN Policy 16.5 (previously OPTN Policy 16.6): • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).
Explanation	Form ORG-063 Verification of Donor Information and Packaging/Labeling was updated to reflect the change from OPTN Policy 5.0 to OPTN Policy 16 on July 1, 2015. For the cases listed, OPO staff utilized a version of the form that was printed from the OPO EMR which did not include the updated language. There was not clear communication that the OPO form ORG-063 should be used in order to ensure compliance. <u>Root cause</u>: Lack of communication between quality and organ staff as to proper form to use.
Corrective Action Plan and Estimated Completion Dates	1. The best practices "Verification for Accuracy of Documentation and Packaging of Transplantable Organs" form provided by the UNOS audit staff will be implemented (has been assigned ORG-097 as an identifier). It will be referenced in policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs and ORG A13.000 Packaging and Labeling of Organs. This form and policy updates will be implemented no later than October 5, 2016.

	2. All Organ Services staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates prior to implementation and no later than October 5, 2016. Effectiveness assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
Area of Non-Compliance #9	The following donor record did not have documentation of two individuals verifying organ and vessel packaging and labeling at the same time as required by OPTN Policy 16.5 (previously OPTN policy 16.6). Cross clamp was 4/20/2016 – 0309. First verifier signed the generic form on 4/20/16 – 0405. Second verifier signed the form on 4/22/16 – 1313. • [redacted]
Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policies 2.2, pronouncement of death and archived sample, 2.5, 2.15C (previously 2.15B), and 16.5 (previously OPTN Policy 16.6).

Explanation	The second verifier failed to sign the form when the verification took place and instead signed the form two days later when it was caught by another coordinator during review. Root cause: [redacted] did not follow policy.
Corrective Action Plan and Estimated Completion Dates	1. The best practices "Verification for Accuracy of Documentation and Packaging of Transplantable Organs" (has been assigned ORG-097 as an identifier) form provided by the UNOS audit staff will be implemented. It will be referenced in policy ORG A11.000 Surgical Recovery, Perfusion and Preservation of Organs and ORG A13.000 Packaging and Labeling of Organs. This form and policy updates will be implemented no later than October 5, 2016. 2. [redacted] Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm two individuals have verified organ and vessel packaging and labeling at the same time. These forms will be updated and effective no later than October 5, 2016. 3. All Organ Services staff and Organ Clinical Quality Assurance Coordinators will be trained on the form and policy updates prior to implementation and no later than October 5, 2016. 4. Previously, reportable events were not consistently initiated when signatures were missing from ORG-063, but instead correction requests were initiated. WI-ORG-068 will be created and reflect that if the verification does not take place at the same date/time for both coordinators involved, or if there is a missing signature, date, or time on the "Verification for Accuracy of Documentation and Packaging of Transplantable Organs" (has been assigned ORG-097 as an identifier) form a reportable event must be initiated and a case note must be written by the ORC as to why the procedure was not followed. This will be implemented no later than October 5, 2016 and all Organ Services and Quality Assurance staff will be trained on these changes prior to the implementation date. Effectiveness assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of

<table>
<tr><td></td><td>the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.</td></tr>
<tr><td></td><td>C. Data Validation</td></tr>
<tr><td>Area of Non-Compliance #10</td><td>Validation of data submitted in Tiedi for Deceased Donor Registration (DDR) forms.

5 DDR forms reviewed
4 DDR forms with errors
13 total number of errors
<table>
<tr><th>Donor ID</th><th>Tiedi documentation</th><th>Donor record documentation</th></tr>
<tr><td>[redacted]</td><td>Organ Recovery:
Chest X-ray = Abnormal - left</td><td>Organ Recovery:
Chest X-ray = Abnormal - both</td></tr>
<tr><td>[redacted]</td><td>Organ Recovery:</td><td>Organ Recovery:</td></tr>
</table></td></tr>
</table>

		Date and Time agonal phase begins (systolic BP < 80 or O2 sat. < 80%): 04/17/2016 - 12:12 The OPO did not provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death.	Date and Time agonal phase begins (systolic BP < 80 or O2 sat. < 80%): 04/17/2016 - 12:16 The OPO had data available through 12:22 in the donor record. Time of death is 04/17/2016 - 12:25	
	[redacted]	**Procurement and Authorization:** Date and time authorization obtained for organ donation: 04/08/2016 - 14:39 **Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Other/Specify: No medications listed.	**Procurement and Authorization:** Date and time authorization obtained for organ donation: Unable to verify. (time) **Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Other/Specify: Keppra	

		Organ Recovery: The OPO did not provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death. Liver Biopsy: No	**Organ Recovery:** The OPO had data available through 01:04 in the donor record. Time of death is 04/20/2016 - 01:08. Liver Biopsy: Yes, received biopsy report from the transplant center on 05/03/2016.	
	[redacted]	**Clinical Information:** Serology: HTLV Serology Results: Not Done West Nile Serology Results: Negative West Nile NAT Results: Not Done	**Clinical Information:** Serology: HTLV Serology Results: Negative West Nile Serology Results: Not Done West Nile NAT Results: Negative	

		Donor Management: (Any medications administered within 24 hours prior to cross clamp.) Diuretics: No Arginine Vasopressin: No Inotropic Medications at Time of Cross Clamp: No	**Donor Management:** (Any medications administered within 24 hours prior to cross clamp.) Diuretics: Yes, Mannitol given in the OR Arginine Vasopressin: Yes Inotropic Medications at Time of Cross Clamp: Yes, Levophed running at cross clamp per anesthesia record.	
Requested Action(s)	Please make corrections in Tiedi on these DDRs and submit a corrective action plan to ensure that similar errors do not occur in the future.			
Explanation	[redacted] The final chest x-ray was entered into the OPO electronic medical record after the DDR was validated. The chest x-ray result that was entered was the last result documented at the time of DDR validation. The DDR was not updated when the final chest x-ray was updated in the OPO EMR. [redacted] The DDR in Tiedi will validate without the serial data being entered; therefore, there was no indicator to the person validating the information that the serial data was missing. Many of the data fields within Tiedi are now completed by importing data from our electronic medical record into the DDR, but the serial data is not included in the import and must be hand entered by a coordinator prior to validating the document. [redacted] The date and time authorization was obtained for organ donation: this case was a DCD case. The family completed authorization and a partial DRAI on 4/17/16 at 16:29. After further discussions with the doctor, the family decided to wait an additional 24 hours to withdraw care. The following day, 4/18/16 the family decided to withdraw care and move forward with the donation process. The Family Service Coordinator had the family amend the authorization for when they decided to proceed with the donation process on 4/18/16. When			

	the authorization was Reviewed, this was brought to the attention of the Manager, Business Analytics & Regulatory Compliance and the Manager, Family Services. The Family Service Coordinator was counseled to change the authorization date/time back to the date/time it was completed (4/17/16 16:29) and was re-trained that the date/time of an authorization should always be documented when it is completed and not changed if there is a delay in the case. In regards to the Keppra not being documented in Tiedi- this was due to a coordinator not following policy on what is documented on the DDR. The DDR in Tiedi will validate without the serial data being entered; therefore, there was no indicator to the person validating the information that the serial data was missing. Many of the data fields within Tiedi are now completed by importing data from our electronic medical record into the DDR, but the serial data is not included in the import and must be hand entered by a coordinator prior to validating the document. In the OPO electronic medical record, the liver data page had biopsy performed marked as no, but at the bottom of the page it was noted that a biopsy would be performed at the accepting transplant center. When the biopsy results were received, they were not entered on the liver data page and should have been, as that information is imported from the EMR into Tiedi. [redacted] Multiple coordinators entered serology results into the serology result page in the OPO EMR and that information is eventually imported over to Tiedi to complete the DDR. The information entered was not Reviewed against the results in the chart and, therefore, errors were made documenting which serology tests were performed. In regards to the data entry errors surrounding medications administered, the QA Coordinator validating the DDR did not check the Intraoperative Management page in the OPO record or the anesthesia flowsheet. <u>Root cause:</u> Lack of alignment of processes for Organ department staff entering and validating DDRs and Quality Services staff performing quality check of donor record. Lack of training and competency.
Corrective Action Plan and Estimated Completion Dates	1. All information identified by site surveyors was corrected in Tiedi September 18, 2016. 2. When the Clinical Quality Coordinator is ready to close a chart, one of the final steps will be to run an audit report to see if any fields that populate into the DDR have changed since the date the DDR was submitted. This will be included on WI-ORG-068 Organ Chart QA Process. These will be implemented no later than October 5, 2016.

	3. All Quality Assurance staff will be trained on the process change and the work instruction no later than October 5, 2016. 4. A report that can pull the serial data from the OPO EMR into the DDR will be implemented no later than October 13, 2016. 5. [redacted] form ORG-052 DCD Clinical Pathway will be updated to reflect that vital signs must be documented every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between the start of the agonal phase and cardiac death. These updates will be made by October 5, 2016. 6. All Quality Assurance and Organ Recovery staff will be trained on the process change, updated pathway, and updates to the work instruction no later than October 5, 2016. 7. Family Services staff will receive education regarding the completion of the authorization/disclosure paperwork, what to do if a case is delayed for any reason, and the proper way to make error corrections. This will all occur by October 5, 2016. 8. Organ staff will be retrained on marking the liver data page appropriately when a biopsy is performed, even if it is not performed locally, as well as the effects of not marking this information appropriately. This will be completed by October 5, 2016. 9. A checklist (has been assigned ORG-098 Case Hand Off Report as an identifier) will be made for Organ Recovery Coordinators to complete at the end of a case in order to communicate to the QA staff any testing that needs followed up on post case (i.e. pending tests, pending biopsy reports, etc.). The checklist will be implemented no later than October 5, 2016 and staff will be trained on the form. 10. Quality Assurance Coordinators and Organ Recovery Coordinators will be re-trained regarding entry of biopsy results on the anatomy pages in the OPO EMR to ensure correct information is imported into the DDR. Retraining will be completed with appropriate staff no later than October 5, 2016. 11. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016. 12. These changes will be reflected in [redacted] work instruction WI-QS-009 Completing the Deceased Donor Registration and WI-ORG-068 Organ Chart QA

Process. Additionally, the places to look in the donor record for certain information will be added to the WI-QS-009 to ensure that all locations for information have been checked prior to DDR validation. This will be implemented no later than October 5, 2016.

13. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016.

Effectiveness assessment:
Compliance will be measured through our internal audit process. Internal audit 004 "Organ Donor Suitability & Positive Serologies" will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart on cases where organ and tissue was recovered. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance. The corrective action process will be followed for any non-conformances identified.

The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement.

The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.

<table>
<tr><td>Area of Non-Compliance #11</td><td>Validation of data submitted for Donor Summaries

5 donor summaries were reviewed
2 of 5 summaries with errors

<table>
<tr><th>Donor ID</th><th>Tiedi documentation</th><th>Donor record documentation</th></tr>
<tr><td>[redacted]</td><td>Donor Information:
Admit Date: 02/11/2016 - 01:00</td><td>Donor Information:
Admit Date: 02/11/2016 - 02:19</td></tr>
<tr><td>[redacted]</td><td>Medical and Social History:
History of hypertension, compliant with treatment: Yes

Medical and social history comments:
"Patient did have HTN for the past 5 or 6 years and was on medications for control."

Infectious Diseases:
Anti-HTLV I/II: Not Done</td><td>Medical and Social History:
History of hypertension, compliant with treatment: Unable to verify

Medical and social history comments:
Per mother on DRAI, the donor "never took medication for it."

Infectious Diseases:
Anti-HTLV I/II: Negative</td></tr>
</table>
</td></tr>
<tr><td>Requested Action(s)</td><td>Please provide a corrective action plan that shows how the OPO will ensure the accuracy of data entered into DonorNet.</td></tr>
</table>

Explanation	[redacted] The date/time of admission was changed by the tissue team after they verified the information with the hospital face sheet. There is no process for the organ staff to know to change this in UNET. [redacted] The donor hospital record listed that the patient was compliant with taking medication for their BP which did not align with what the historian provided during the health assessment interview. Root cause: Lack of alignment of processes for Organ department staff entering and validating DonorNet Summaries and Quality Services staff performing quality control of the donor record. No hierarchy of priority of information to be documented.
Corrective Action Plan and Estimated Completion Dates	1. WI-FS-008 Referral process will be updated to reflect that the FSC or ORC who performs the first onsite for the referral will verify the date/time of admission per the hospital face sheet and ensure that the documentation in the OPO EMR is correct. The work instruction will be updated and all FSCs and ORCs trained on the changes no later than October 5, 2016. 2. The Anti-HTLV I/II result was updated to Negative in the DDR on September 18, 2016. We are unable to change the medical-social history comments within UNET. 3. The QA process for verifying serology results in UNET/TIEDI will be updated to reflect that all serology results documented will be read aloud by one Clinical Quality Assurance Coordinator and verified in UNET/TIEDI by a second Clinical Quality Assurance Coordinator. If the donor also donated tissue, this will have to be performed with a Tissue Clinical Quality Assurance Coordinator to ensure that the final serology results have been received and that all test results are included prior to validation. This will be implemented no later than October 5, 2016. 4. These changes will be reflected in [redacted] work instruction WI-QS-009 Completing the Deceased Donor Registration. This will be implemented no later than October 5, 2016. 5. The Clinical Quality Assurance Coordinators will be trained on these changes no later than October 5, 2016. 6. A report will be created enabling Quality Assurance staff to monitor the tests that are pending for both organ and tissue cases so that they can obtain tests and ensure compliance. This will be implemented no later than October 13, 2016.

	7. WI-QS-009 Completing the Deceased Donor Registration will be updated to explain ``what should be done if the information in the hospital chart differs from what the historian reports in the UDRAI. The updates will be completed and Quality Assurance Coordinators and Organ Recovery Coordinators will be trained on the updates by October 5, 2016. Effectiveness assessment: Compliance will be measured through our internal audit process. Internal audit 004 "Organ Donor Suitability & Positive Serologies" will have an audit item added where the auditor will check the serology results in UNET to ensure they match what is documented in the chart. This audit was started September 23, 2016. Any non-conformances will be reported to the Manager, Business Analytics & Regulatory Compliance, and the corrective action process will be completed to correct any non-conformances identified. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
	D. Priority UNOS Member Quality Management Review – MPSC Review
Section II – Policy Review and Process Validation	**A. OPTN Policy 2.6 Deceased Donor Blood Type Determination and Reporting**
Area of Non-Compliance #12	The OPO submitted the following internal policies, procedures and/or protocols to UNOS for review: • Title: ABO Confirmation, Department: ORG, Section: A, Policy: 17.000, Revision: 11, Effective Date 02/01/2016 As part of the survey process, OPO protocols/polices were reviewed to verify compliance with OPTN Policies. The findings of this review are as follows:

<table>
<tr><td></td><td>
<table>
<tr><th>Required Element</th><th>Element in Protocol</th></tr>
<tr><td>Tests were completed using two separate blood samples</td><td>Verified</td></tr>
<tr><td>Protocol to resolve conflicting primary blood types</td><td>Verified</td></tr>
<tr><td>Verification that two individuals performing blood type reporting each consulted source documents</td><td>Verified</td></tr>
<tr><td>Verification occurs prior to the match run or in cases of accelerated donation, verification occurs prior to organ release to the transplant hospital.</td><td>Unable to verify, accelerated donation element is not present.</td></tr>
</table>

During the onsite review, site surveyors conducted an interview with two Organ Recovery Coordinators (ORCs) about how they perform ABO verification. Site surveyors validated that OPO staff practices align with the OPO's policies and procedures related to OPTN Policy 2.6.</td></tr>
<tr><td>Requested Action(s)</td><td>Please provide a corrective action plan to ensure compliance with OPTN Policy 2.6.</td></tr>
<tr><td>Explanation</td><td>Language regarding how ABO verification must occur in the case of an accelerated donation was not incorporated when updating policy ORG A17.000 ABO confirmation.

<u>Root Cause:</u>
Lack of a process to ensure all regulation updates are implemented in policy and practice.</td></tr>
<tr><td>Corrective Action Plan and Estimated Completion Dates</td><td>1. Policy ORG A17.000 ABO Confirmation will be updated to include language regarding cases of accelerated donation and verification occurring prior to organ release to the transplant hospital. The policy updates will be implemented no later than October 5, 2016.</td></tr>
</table>

	2. All Organ Services staff and Quality Staff will be trained on the policy updates prior to implementation and no later than October 5, 2016. 3. When UNOS, CMS, or other regulatory policy language is updated, the Manager, Business Analytics and Regulatory Compliance is notified of changes via email from all of the regulatory bodies (UNOS, CMS, etc.). The Manager, Business Analytics and Regulatory Compliance or designee will notify appropriate department leaders that policy updates affecting their respective department(s) may be necessary. The appropriate department leader(s) will be responsible for updating all affected policies, forms, and/or work instructions in [redacted]s document management system by the deadline provided by the Manager, Business Analytics and Regulatory Compliance or designee as he/she deems appropriate. The Manager, Business Analytics and Regulatory Compliance or designee will review the updated policies, forms, and work instructions to ensure all information is updated according to regulatory policy language and becomes effective as defined by the regulatory body. Corrections or additional updates may be required by department leaders. Department leaders will be responsible for retraining of staff as appropriate. The Quality Systems Coordinator will update the internal audit matrixes within the same time frame that is given to department leadership to make policy updates. The updated audit matrixes will then be reviewed for accuracy by the Manager, Business Analytics and Regulatory Compliance. Additionally, prior to any audit beginning, the Quality Systems Coordinator will ensure a review of the most current UNOS and CMS policies and ensure alignment of the audit with these policies. 4. Policy ORG D2.000 Implementation of new UNOS policies and QS B1.000 Policies and Procedures Document Control will be updated to reflect these changes and implemented no later than October 5, 2016. 5. Organ Services leadership staff, the Manager, Business Analytics & Regulatory Compliance and the Quality Systems Coordinator will all be trained on the policy updates prior to implementation and no later than October 5, 2016. <u>Effectiveness Assessment:</u> The Quality Systems Coordinator will continue to perform annual audits to ensure regulatory policy language is accurately reflected in all applicable internal policies.

	An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
	B. OPTN Policy 2.6.B Deceased Donor Blood Subtype Determination
Area of Non-Compliance #13	The OPO submitted the following internal policies, procedures and/or protocols to UNOS for review: • Title: ABO Confirmation, Department: ORG, Section: A, Policy: 17.000, Revision: 11, Effective Date 02/01/2016 As part of the survey process, OPO protocols/policies were reviewed to verify compliance with OPTN Policies. The findings of this review are as follows:

Required Element	Element in Protocol
Tests were completed using two separate blood samples	Verified
Samples used were pre red blood cell transfusion	Unable to verify
If conflicting subtype results, the subtype must not be reported	Verified

During the onsite review, site surveyors conducted an interview with two Organ Recovery Coordinators (ORCs) about their knowledge regarding the process for subtyping of blood group A donors. Based on staff interviews, there was a knowledge gap regarding the content of the OPO's Policy 17.000, Revision: 11 and the OPO's staff practices.

During the interviews, it was determined that staff were inconsistent in verbalizing the requirement for pre red blood cell transfusion samples in subtyping, confusing pre-transfusion with hemodilution.

Requested Action(s)	Please provide a corrective action plan to ensure compliance with OPTN Policy 2.6.B.
Explanation	A knowledge gap was identified surrounding pre-transfusion versus hemodilution and needs to be corrected with the Organ Services department. Root Cause: Lack of training and competency assessment of pre-transfusion samples and hemodilution.
Corrective Action Plan and Estimated Completion Dates	1. All Organ Services staff will receive retraining regarding subtype determination. Education will include rationale for subtyping, rationale for why a pre red blood cell transfusion sample is needed and how that differs from a pre-transfusion sample for performing a hemodilution, as well as the negative effects that could come about if this policy requirement was not fulfilled. The training and demonstrated competency will be completed no later than October 5, 2016. 2. [redacted] Form ORG-002 Clinical Pathway and ORG-052 DCD Clinical Pathway will be updated to reflect that the AOC will confirm ABO in the EMR. These forms will be updated and effective no later than October 5, 2016. 3. The Organ Services new coordinator orientation will be updated to include the information outlined in the step above. This update will be completed no later than October 5, 2016. Effectiveness Assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000.

	An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016.
	C. OPTN Policies 1.2 Definitions and 2.15.B Pre-recovery Verification – No Requested Action
Section III – Data Submission	**A. Deceased Donor Registrations (DDRs) forms**
Area of Non-Compliance #14	[redacted] had the following late DDR submissions between July 1, 2014 – July 1, 2016. There were 7 of 338 (2%) late DDR submissions during this time period. See below for details.

Donor ID	Last Name	First Name	Date Donor Added	DDR Expected Date	Date DDR First Validated	Days Over-due
[redacted]	[redacted]	[redacted]	15NOV2014	18DEC2014	19DEC2014	1
[redacted]			11FEB2016	15MAR2016	20MAR2016	5
[redacted]			11FEB2016	15MAR2016	20MAR2016	5
[redacted]			12FEB2016	17MAR2016	20MAR2016	3
[redacted]			13FEB2016	18MAR2016	21MAR2016	3
[redacted]			01APR2016	06MAY2016	07MAY2016	1
[redacted]			03APR2016	06MAY2016	07MAY2016	1

	DDR forms must be submitted within 30 days as required by Policy 18.1, Table 18-1 (previously OPTN Policy 7.2).
Requested Action(s)	Please submit a corrective action plan to ensure that DDR forms will be submitted within the required thirty days as required by Policy 18.1 (previously OPTN Policy 7.2).
Explanation	During the time period specified, the manner in which DDRs are completed was updated but there was a lot of confusion among coordinators on how to do this and who was responsible for completing the DDR in a timely manner. Who was responsible for the completion of the

	DDR was not being formally tracked or enforced in any way. Because of volume and process changes, some of the DDRs were completed outside of the 30-day window specified. Root Cause: Lack of alignment of processes for Organ department staff entering and validating DonorNet Summaries and Quality Services staff performing quality control of the donor record.
Corrective Action Plan and Estimated Completion Dates	1. At the conclusion of a case, the Organ Recovery Coordinators are to complete the DDR Entry and Summary page in the electronic medical record system. When the Feedback document is completed in UNET by the Clinical QA Coordinator or Quality Coordinator, they will assign a task in the electronic medical record for the final two Organ Recovery Coordinators on the case to complete any of the DDR Entry and Summary page that has not yet been completed. The ORCs will have 10 calendar days to complete this task. Once the task is marked as complete in the EMR, it will send an email to the quality staff who assigned the task stating that the task has been closed. This will alert the quality staff that the DDR is ready to be Reviewed and validated. 2. Policy ORG-C6.000 Data Submission, WI-QS-009 Completing the Deceased Donor Registration, and WI-QS-010 Completing the Donor Organ Disposition will all be updated to reflect the changes outlined above. These updates will be effective no later than October 5, 2016. 3. All Organ Services staff, Quality Assurance Coordinators and Quality Coordinators will be trained on these changes prior to implementation and no later than October 5, 2016. 4. A report will be created that is sent daily to the Manager, Business Analytics & Regulatory Compliance showing pending Feedback, PTRs, and DDR information. Pending reports that are due within 10 days will be highlighted and the Manager, Business Analytics & Regulatory Compliance will be responsible for ensuring reports are completed on time. This update will be effective no later than October 13, 2016. Effectiveness Assessment: The current organ chart QA process will be updated to be completed in two parts. An initial QA check of critical information including but not limited to the Authorization/Disclosure, UDRAI documents, pronouncement of death documentation, ABO verification, hemodilution, serology results, verification an U/A was performed within 24 hours of cross clamp, accuracy of the Verification of Donor Information form (ORG-063), accuracy of the Verification of

	Accuracy of Documentation & Packaging of Transplantable Organs form (ORG-097), and accuracy of the admission date and time will be performed to ensure critical items identified in this CAP are completed accurately. ORG-002 Clinical Pathway will also be reviewed for completeness at this time. This initial check will be initiated within 10 days of case completion and will be documented on form ORG-085 Organ Chart QA Checklist. All non-conformances will be tracked through the reportable events process per policy QS A1.000. An internal quality committee will review all non-conformances on a monthly basis to ensure they were resolved according to company policy and review any trends identified. If trends are identified, the quality committee will perform an analysis to determine the root cause of the trend and recommend proper corrective actions to implement. The results of all third party audits will be reported to the CEO, and Advisory and Executive Boards. This will be added to policy QS A6.000 Third Party Inspection no later than October 5, 2016. Additionally, monthly, [redacted] will request data submission compliance reports from UNOS and verify compliance of all reports. A corrective action process will be implemented in the event [redacted] is out of compliance.
	B. Donor organ disposition (feedback) – No Requested Action
	C. Potential Transplant Recipient (PTRs) refusal codes – No Requested Action
Section IV	**A. Monthly Death Notification Information**
Area of Non-Compliance #15	UNOS reviewed the OPO's methodology for reporting death notification information in UNet. Two donor records were reviewed to determine the accuracy of the OPO's use of the definition of an "Eligible Death" as defined in OPTN Policy 1.2. The number of donor records included all brain dead non-eligible donors < 71 years old. The review identified two donors the OPO should have reported as Eligible. • [redacted] • [redacted]

Requested Action(s)	Please complete a Death Notification Record (DNR) for each incorrectly reported donor and provide a corrective action plan detailing how the OPO will ensure compliance in reporting an eligible death as defined in OPTN Policy 1.2.
Explanation	The Manager, Organ Services had recently assumed the responsibility of classifying referrals as an "eligible death" and mistakenly classified these two referrals incorrectly. Additionally, there was not a system to check the accuracy of the classification; the accuracy of information reported was dependent upon one person making the determination by themselves. Root Cause: Lack of training and lack of a QA process.
Corrective Action Plan and Estimated Completion Dates	1. The OPO donor records for ABH1141 and ABLN458 have been updated to reflect that they were both eligible donors. Death Notification Records were created in UNET for [redacted] and [redacted] on September 14, 2016. 2. The Manager, Organ Services or designee will be required to determine referral classification no less than once per week and a designated Quality team member will be required to review the referral classifications of the Manager, Organ Services or designee no less than once per week. These individuals will be required to discuss referral classification in the event of a disagreement. These changes will be implemented no later than October 5, 2016. 3. The Manager, Organ Services or designee will indicate the referral classification in the electronic medical record system. A designated Quality team member will write "Verified" upon verification and agreement with Manager, Organ Services' referral classification in the appropriate comments section in the electronic medical record system, which will signify review of the eligibility criteria. These changes will be implemented no later than October 5, 2016. 4. Policy ORG C6.000 Data Submission will be updated to reflect that the Manager, Organ Services or designee and a member of the Quality team will make the determination of "eligible death" together prior to that information being entered into UNET. The policy update will become effective no later than October 5, 2016. 5. The Manager, Organ Services and the Quality staff will be trained on these changes prior to implementation and no later than October 5, 2016. Effectiveness assessment:

	By the tenth of the month, the preceding month's brain deaths and eligibility classifications will be audited by the COO or CEO or designee to ensure compliance with the process.

34451L Death Declaration SBAR, updated 9/6/16

Situation: During a routine OPO site survey at OPO 34451L, Site Surveyors noted irregularities in brain death pronouncement documentation retained for donor records. OPTN Policy 2.2 (#5) The OPO is responsible for verifying that death is pronounced according to applicable laws.

Six donor records (5 records in Attachment 1, and 1 record in Attachment 2) were missing one of the following elements: clinical exam showing absence of all brainstem reflexes, confirmatory test in lieu of aborted apnea tests (donor instability), or brain death pronouncement note signed by an attending physician.

Following the site surveyors' request, the OPO produced (after several hours and contact with donor hospitals) the needed documentation for three of these records. The donor records with missing documentation at the end of the site survey are listed below.

Case #1: [redacted] admitted with massive subarachnoid hemorrhage. Arrived to ED in comatose state. Poor prognosis discussed with family, then declared dead at 416pm by a Nurse Practitioner, "Pt EEG consistent with brain death. 1616 T.O.D. Reviewed c Dr. XXXX XXXXi."

UNOS staff asked for the OPO to provide additional documentation including the definitive neurological exam by physician as well as the hospital's policy on brain death determination (who can determine death).

The OPO was provided an additional clinical note (by NP XXXX XXXX with neurological exam showing "minimal gag reflex." The OPO also included a copy of the EEG report, which is "consistent with electrical silence of the cortex."

Hospital policy (provided by the OPO) requires MD signature for brain death pronouncement. (Page 2 section D)

Case #2: 17 year old female, [redacted] brain death documentation in donor record includes only neurological exam (consistent w BD), note of a second physician being in agreement with exam.

Site surveyors asked the OPO to provide apnea test or other confirmatory test documentation. OPO case notes indicate that the OPO requested an apnea test, but the test was aborted r/t patient instability. No confirmatory test in lieu of an apnea has been provided to date.

Case #3: Donor [redacted] – only death documentation is MD note that reports "I discussed with a large family group the results of the Cerebral Blood Flow Study. The study showed 'No intracerebral blood flow," confirming our suspicions of brain death. Will place the time of death as that of the cerebral Flow Study: 1030 AM today (9/11/2015)."

Surveyors asked the OPO to provide the neurological exam contributing to determination of death. The OPO provided additional clinical notes, but no neurological exam was included. ("No meaningful response") To date, no clinical neurological exam consistent with brain death has been provided.

The lead surveyor asked for an immediate containment plan to prevent any brain death documentation irregularities form occurring. A containment plan was provided before the end of the survey. The OPO

was notified that this situation may be escalated after further management review and that a more robust CAP may be required in the near future.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

[redacted]

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS Certification Number: [redacted]

September 23, 2016
(Via Overnight Mail)

[redacted]

Dear Administrator:

On September 20-22, 2016, the Centers for Medicare & Medicaid Services (CMS) conducted a Medicare substantial allegation (complaint) survey of the [redacted]

Based on the survey results, CMS has determined that the [redacted] does not meet the conditions for coverage for organ procurement organizations (OPOs), and is out of compliance with the condition for coverage listed below. Regulations at 42 CFR § 486, Subpart G for Organ Procurement Organizations require that an organ procurement organization must be in compliance with the applicable conditions for coverage.

42 CFR § 486.344 - Evaluation/Management of Potential Donors & Organ Placement and Recovery

We have determined that the deficiencies are so serious they constitute an immediate threat to patient health and safety. In addition, your OPO was found out of compliance with the following condition for coverage:

42 CFR §486.348: Quality Assessment and Performance Improvement (QAPI)

We have determined that the deficiencies are significant and limit your OPO's capacity to render adequate care and ensure the health and safety of your patients. Enclosed is a complete listing of all deficiencies cited.

Enclosed is form CMS-2567, Statement of Deficiencies and Plan of Correction, documenting the Condition- and Standard-level deficiencies found during the recent survey. All deficiencies cited on the CMS-2567 require a Plan of Correction (PoC). You are required to respond **within five calendar days** of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

An acceptable PoC must contain the following elements:

1. The plan for correcting each specific deficiency cited;
2. Efforts to address improving the processes that led to the deficiency cited;
3. The procedure for implementing the acceptable PoC for each deficiency cited;

4. A completion date for correction of each deficiency cited;
5. A description demonstrating how the OPO has incorporated systemic improvement actions into its Quality Assessment and Performance Improvement (QAPI) program in order to prevent the likelihood of the deficient practice from reoccurring;
6. Procedures for monitoring and tracking to ensure that the PoC is effective and that specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements; and
7. The title of the person responsible for implementing the acceptable PoC.

A PoC for the deficiencies must be submitted by **September 29, 2015**, to:

Centers for Medicare & Medicaid Services
[redacted]
Division of Survey & Certification
[redacted]

The correction dates on the Plan of Correction must be no later than **October 13, 2016**. There will be a review following receipt of a credible allegation of compliance.

You must sign and date the bottom of the first page of the CMS-2567. You should be aware that copies of the Form CMS-2567 and subsequent plans of correction are releasable to the public upon request in accordance with the provisions at 42 CFR § 401.133.

Deficiencies which resulted in non-compliance with the conditions for coverage must be corrected in order for payment for covered organ procurement services to continue. CMS will terminate your participation in Medicare if you do not achieve compliance with the conditions for coverage by **October 18, 2016.**

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request a final Administrative Law Judge (ALJ) review. To do this, you must file your appeal within 60 calendar days after the date of receipt of this decision.

You must file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov. To file a new appeal using DAB E-File, you first need to register a new account by: (1) clicking Register on the DAB E-File home page; (2) entering the information requested on the "Register New Account" form; and (3) clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he is a party or authorized representative. Once registered, you may file your appeal by:

- Clicking the **File New Appeal** link on the Manage Existing Appeals screen, then clicking **Civil Remedies Division** on the File New Appeal screen and,
- Entering and uploading the requested information and documents on the "File New Appeal- Civil Remedies Division" form.

At minimum, the Civil Remedies Division (CRD) requires a party to file a signed request for hearing and the underlying notice letter from CMS that sets forth the action taken and the party's appeal rights. All documents must be submitted in Portable Document Format ("PDF"). Any document, including a request for hearing, will be deemed to have been filed on a given day, if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day. A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files. Correspondingly, CMS will also be deemed to have consented to electronic service. More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E-File Procedures link on the File New Appeal Screen for CRD appeals.

If you do not have access to a computer or internet service, you may file in writing, but must provide an explanation as to why you cannot file submissions electronically and request a waiver from e-filing in the mailed copy of your request for a hearing. The mailed request should be sent within 60 days of receipt of this notice to the following address:

[redacted]

Appeal rights can be found at 42 CFR Part 498. The regulation explains the appeal rights following the determination by CMS as to whether such entities meet the requirements for participation in the Medicare program.

If you have any questions regarding this action, please contact [redacted] of my staff, at [redacted]

Sincerely,

[redacted]

Branch Manager
Non-Long Term Care Certification
& Enforcement Branch

[redacted]

[redacted] Department of Health
[redacted] Family and Social Services Administration
UNOS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/23/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	[redacted]	A. BUILDING _____ B. WING _____	C 09/22/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
[redacted]	[redacted]

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
[redacted]	INITIAL COMMENTS An unannounced substantial allegation survey was conducted by federal surveyors on September 20, 2016 at the [redacted] in [redacted], [redacted] in accordance with the requirements of 42 CFR Part 486, Subpart G for Organ Procurement Organizations. Complaint [redacted]00210101 was substantiated, and an Immediate Jeopardy was identified under the Condition for Coverage found at 42 CFR §486.344: Evaluation and Management of Potential Donors and Organ Placement and Recovery. Other findings included noncompliance with the Condition for Coverage found at 42 CFR §486.348: Quality Assessment and Performance Improvement (QAPI). The President/CEO and other staff members were notified of all findings during an exit conference held at the [redacted] on September 20, 2016 at 4:15 p.m. The President/CEO was notified of the Immediate Jeopardy on September 22, 2016 at 12:50 p.m.	[redacted]		
[redacted]	486.344 EVAL/MGT OF PTNTL DONORS/ORG PLCMNT & RCVRY The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor. This CONDITION is not met as evidenced by: Based on document review and interview, the OPO failed to ensure compliance with written	[redacted]		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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[redacted]	Continued From page 1 protocols for donor evaluation that meet current standards of practice. This deficient practice has the potential to effect any future donor's. Findings include: 1) An Immediate Jeopardy was identified as a result of the OPO's failure to verify and document that the potential donor has been pronounced dead in accordance with applicable legal requirements of local, State, and Federal laws, or the equivalent, with supporting documentation, in three of nine donor records reviewed (Donor #1, Donor #2, Donor #3). See [redacted] for details. [redacted] 486.344(b)(1) POTENTIAL DONOR EVALUATION [The OPO must do the following:] Verify that death has been pronounced according to applicable local, State, and Federal laws. This STANDARD is not met as evidenced by: Based on record review and interview, the OPO failed to verify and document that the potential donor has been pronounced dead in accordance with applicable legal requirements of local, State, and Federal laws, or hospital policy, with supporting documentation, for three of nine donor records reviewed (Donor #1, Donor #2, Donor #3). Findings include: During an interview on September 20, 2016 at 9:15 a.m., the Manager, Business Analytics & Regulatory Compliance stated, "There is no state statute for brain death." When an alternative	[redacted]		

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[redacted]	Continued From page 2 source was requested for the OPO's point of reference for the verification of brain death, the "Guidelines for Determination of Brain Death," [redacted] State Medical Association, March 22, 2010, was provided for "Adult Diagnostic Criteria - Patients Above 18 Years of Age," the Manager, Business Analytics & Regulatory Compliance indicated, "This is what we use." When a pediatric point of reference was requested, a copy of the "Proposed Guidelines for the Determination of Brain Death in Infants and Children in the State of [redacted] Being Submitted for Approval by the [redacted] State Medical Association" were provided. On September 20, 2016, review of OPO policy entitled "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014, revealed "Purpose: To verify that brain death has been determined and documented using standard clinical practice. 1. The Family Services Coordinator (FSC) will confirm the status of brain death declaration and documentation. 2. The FSC will verify that the following information is included in the brain death note: a. Date and Time of pronouncement b. Physician's signature c. Specific language must be present that states patient has been pronounced dead, impression: brain death or diagnosed brain dead. 3. The FSC should contact the Administrator on Call (AOC) if there is any question concerning the brain death note. Review of donor records on September 20, 2016 at 11:40 a.m. revealed that Donor #1 was admitted to the hospital on January 5, 2015 with massive subarachnoid hemorrhage. According to the progress notes of the hospital record, "PT	[redacted]		

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[redacted]	Continued From page 3 (patient) EEG (electroencephalogram) consistent with brain death 1616 TOD (time of death). Reviewed with Dr. A." The brain death note was signed by a nurse practitioner, which is not in compliance with OPO policy "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014. The brain death note did not include the results of a neurological exam in accordance with the "Guideline's for Determination of Brain Death," [redacted] State Medical Association, March 22, 2010. Review of donor records on September 20, 2016 at 11:40 a.m. for Donor #2 revealed documented results of a cerebral blood flow study with no corresponding neurologic criteria for brain death in accordance with the "Guidelines for Determination of Brain Death, [redacted] State Medical Association, March 22, 2010. Review of donor records on September 20, 2016 at 11:40 a.m. for Donor #3 revealed that documentation for a 17-year-old potential donor included only a neurological exam consistent with brain death. Donor #3 had an aborted apnea test due to instability but no further confirmatory testing. According to the "Proposed Guidelines for the Determination of Brain Death in Infants and Children in the State of [redacted] Being Submitted for Approval by the [redacted] State Medical Association, Issues to be considered and protocol to be followed relating to brain death examination: 4. Apnea testing: b. If the apnea test cannot be performed as a result of a medical contraindication or cannot be completed because of hemodynamic instability, desaturation to <85%, or an inability to reach a Paco2 of (symbol	[redacted]		

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	[redacted]	A. BUILDING _____ B. WING _____	C 09/22/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
[redacted]	[redacted]

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[redacted]	Continued From page 4 for greater than or equal to) 60 mm Hg, an ancillary study should be performed." The OPO did not verify that brain death had been determined and documented using standard clinical practice, in accordance with OPO policy. The donor record did not include any other documentation regarding hospital policy under these circumstances. Interview with FSC-1 on September 20, 2016 at 2:20 p.m. revealed that verification of brain death included ensuring a copy of the brain death note is in the donor's chart, also stating that the brain death should include declaration with date and time, signature "depending on hospital policy," and sometimes a form that Dr. X (Medical Director) uses for declaration. FSC-1 stated that "every hospital has a different brain death policy." If an apnea test is aborted, FSC-1 stated that confirmatory testing "goes by hospital policy." The hospital policy was not included in the specified documentation for verification and documentation that brain death has been pronounced in accordance with standard clinical practice, per OPO policy "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014. These findings were verified with the Manager, Business Analytics & Regulatory Compliance on 9/20/16 at 3:10 p.m., who stated that there should have been clinical exams for Donor #1 and Donor #2 and Donor #3.	[redacted]		
[redacted]	486.348 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program	[redacted]		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	[redacted]	A. BUILDING _____ B. WING _____	C 09/22/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
[redacted]	[redacted]

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
[redacted]	Continued From page 5 designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement. This CONDITION is not met as evidenced by: Based on document review and interview, the OPO failed to implement and maintain a comprehensive Quality assessment and performance improvement (QAPI) program inclusive of performance indicators that are monitored on an ongoing basis and governing body involvement. This deficient practice has the potential to effect any future donor's. Findings include: 1) During interview on September 20, 2016 at 10:20 a.m., the Manager, Business Analytics & Regulatory Compliance stated that there are no benchmarks, indicators, or thresholds as part of the QAPI program but that they are "building it." 2) Upon request for a copy of the QAPI Plan on September 20, 2016 at 10:20 a.m., the Manager, Business Analytics & Regulatory Compliance stated that there is only a draft at this time. 3) During the exit conference on September 20, 2016 at 4:15 p.m., the President/CEO stated that the Governing Board is not notified of reportable events, other than infectious disease transmissions. 4) See Z 200. There is no evidence that a physician's signature or that pronouncement was documented using standard clinical practice in accordance with OPO policy. 486.348(a) COMPONENTS OF A QAPI	[redacted]		

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[redacted]	Continued From page 6 PROGRAM The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained. This STANDARD is not met as evidenced by: Based on document review and interview, the OPO failed to demonstrate objective measures to evaluate performance with regard to OPO activities and actions to ensure that performance improvements are sustained. This deficient practice has the potential to effect any future donor's. Findings include: 1) During an interview on September 20, 2016 at 10:20 a.m. with the Clinical Quality Assurance Coordinator she indciated she is responsible for completeness and accuracy of the donor chart. The Clinical Quality Assurance Coordinator stated that the death note should include a note that the donor is brain dead, signed, dated, and timed or that the family is wanting to withdraw care. The Clinical Quality Assurance Coordinator stated that the death notes are not flagged as a reportable event requiring review and assignment to a manager. The Clinical Quality Assurance	[redacted]		

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[redacted]	Continued From page 7 Coordinator stated that when corrections are made successfully the chart is closed. There is no evidence of monitoring to ensure that the corrections are sustained. 2) Review of the Organ Donor Records Audit on September 20, 2016 at 10:20 a.m. revealed "Audit item 4.i. Time and date of pronouncement of death; I. copy of declaration of death note." There is no evidence that a physician's signature or that pronouncement was determined and documented using standard clinical practice, in accordance with OPO policy "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014.	[redacted]		